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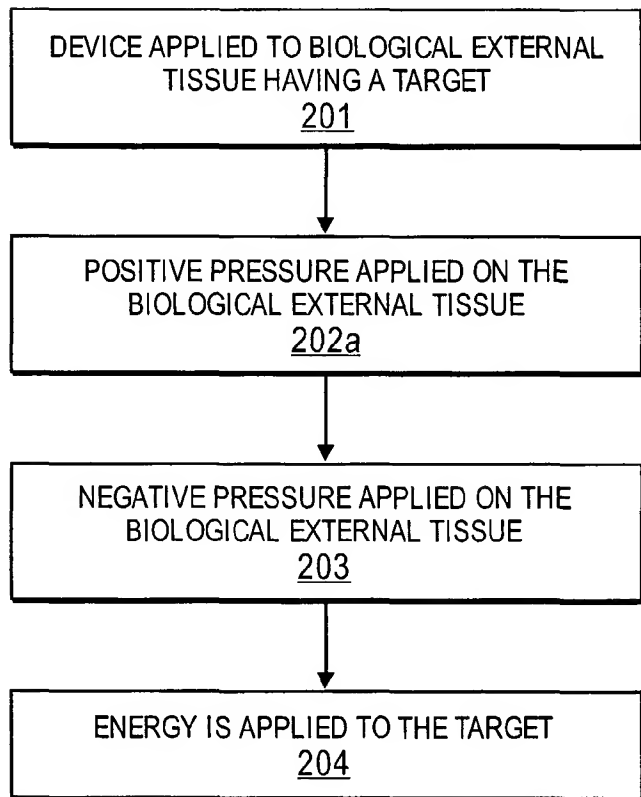
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(54) Title: APPARATUS HAVING A COOLING MATERIAL AND REDUCED PRESSURE TO TREAT BIOLOGICAL EXTER-
NAL TISSUE



(57) Abstract: Devices and methods having a cooling material and reduced pressures to treat biological external tissue using at least one energy source are disclosed. The cooling material may be water, ethyl alcohol, and/or any other material having a vapor pressure below atmospheric pressure. The energy source may be incoherent light, coherent light, a radio frequency, ultrasound, a laser, and/or any other type of energy that can be applied through the device. The features of various embodiments of the device include the generation of positive pressure and/or negative pressure through one or more pressure conduits, the application of an object within a recess of the device, and measurements through various sensors on the device. These sensors may be monitored and/or controlled through a display element having rows and columns of pixels on the device. The device may be a handheld device or an add-on to existing devices in some embodiments, and may include skin color sensors, temperature sensors, motion sensors, vapor pressure sensors, material sensors, and/or capacitance sensors.

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APPARATUS HAVING A COOLING MATERIAL AND REDUCED PRESSURE TO TREAT BIOLOGICAL EXTERNAL TISSUE

RELATED APPLICATIONS

[0001] The present application is a Continuation-In-Part to U.S. Patent application serial number 10/841,273, filed on May 7, 2004.

FIELD OF THE INVENTION

[0002] The present invention relates to methods and devices useful in modification, treatment, destruction, and/or removal of tissue.

BACKGROUND OF THE INVENTION

[0003] Devices utilized in dermatological treatments often incorporate light based energy sources or high frequency rf electrical energy sources. Examples of such devices are described in U.S. Patent No. 6,511,475. Some devices include both technologies.

A. Lasers and light-based technologies

[0004] Lasers and light-based devices have been used for many years in the treatment of dermatological conditions. Soon after the laser was invented in 1957, medical researchers started to explore its use for a wide range of dermatological procedures. In recent years, especially since the mid-90's, the technology has been commercialized into numerous different devices that remove unwanted hair, wrinkles, fine lines and various facial blemishes ("skin rejuvenation"), tattoos, and vascular and pigmented lesions. Because of the short treatment time, virtually no patient "down-time" and fewer side effects, several of these laser- or light-based treatments have become more widely used than the conventional alternatives.

[0005] Light energy, when applied directly to the human body, is absorbed by the target chromophore; by the hemoglobin in the blood; the water in the skin; the

melanin in the skin; and/or by the melanin in the hair follicles, depending on the wavelength(s) of the light used. Lasers generating different wavelengths of light were found early on to have different properties, each being preferable for specific procedures. In addition to lasers that emit a coherent, monochromatic light, several manufacturers have also introduced devices that emit light of a wide range of wavelengths that practitioners then filter to select the appropriate wavelength for a specific treatment. These “multi-wavelength” or “multi-application” light-based devices have the advantage of performing several different aesthetic treatments, and thus costing the practitioner less than purchasing several lasers individually.

[0006] Figure 1a is a diagram showing the various layers of the skin and potential targets for photo therapy and/or electrical therapy. When light energy first impacts the skin, it encounters the epidermis, the outer most layer of skin. One of the substances that comprise the epidermis is melanin, the brown pigmentation that most of us have in our skin. Darker individuals have more melanin than lighter ones. For very dark individuals, melanin may comprise more than 20% of the epidermis. For light skin individuals, melanin may comprise only 1 to 2% of the epidermis.

[0007] Melanocytes in the upper epidermis generate this melanin in response to sunlight. The melanin migrates from the cell and forms a protective umbrella over the fibroblasts and other cells in the skin. The melanin absorbs harmful UVA and UVB radiation that can cause cell damage. It also absorbs visible light, absorbing blue light more than red light.

[0008] The epidermis is very thin as it is only 50 to 100 microns in thickness. Consequently, despite the strong absorption by melanin, a reasonable percentage of the light passes through the epidermis into the upper layer of the dermis. For a fair skin person, as little as 15% of the light in the visible portion of the spectrum is absorbed in the epidermis. For a darker person, the percentage absorbed can be more than 50%.

[0009] After passing through the epidermis, the light impacts a region called the dermal plexus. This is a thin region at the outer most region of the dermis. It contains a high concentration of small capillary vessels that provide nourishment to the overlying epidermis. The blood in these vessels absorbs between 35% and 40% of the visible portion of the light that impacted the skin.

[0010] Clearly for a moderate to dark skin individual, the majority of the visible portion of the spectrum is absorbed in the epidermis and the dermal plexus. Very little energy remains to treat a target located deeper than the dermal plexus.

[0011] Figure 1b shows the percentage of incident energy transmitted, as a function of wavelength, through the epidermis for three different skin types. The figure shows a low percentage of the incident energy in the visible portion of the spectrum is transmitted through the epidermis. The energy not transmitted is absorbed, resulting in a rise in temperature of the epidermis and possibly resulting in the burning of the tissue.

[0012] Figure 1c shows the percentage of incident energy transmitted through the dermal plexus for two different levels of blood concentration (shown as ratios of blood to the rest of the tissue in a given volume). As in the epidermis, the energy not transmitted is absorbed and can produce burning. More importantly, the energy absorbed in the dermal plexus is not available to heat a target such as collagen or tattoo ink that is located beneath the dermal plexus. By reducing the concentration in half, the energy transmitted is doubled.

B. High Frequency rf Electrical Devices

[0013] In addition to light based therapies, high frequency rf electrical energy is also becoming common in devices used to treat wrinkles, unwanted hair and unwanted vascular lesions. One of the basic principles of electricity is an electric current passing through a resistive element generates heat in that element. The power dissipated in the element is proportional to the square of the electrical current and also proportional to the resistance of the element. The heat generated is the product of the power times the length of time the power is being dissipated.

[0014] A second basic principle of electricity is the electric current seeks the path of least resistance. If two or more such paths exist, the current divides itself proportionally to the resistance of each path. For example, if two such paths exist and one path is twice the resistance of the other, twice the current will pass through the path with the lesser resistance than passes through the path with more resistance. The distribution of power and energy is also in the ratio of the resistances. In the current example, two times the power is dissipated in the lower resistance path than in the higher path. The path with the lesser resistance will heat at twice the rate as the higher resistance path.

[0015] High frequency rf energy in dermatology works on the principles described above. In this case, the various tissues and components of the body are the electrical resistors. As the rf current passes through these tissues, energy is dissipated and the temperature of the tissue rises. If the tissue is a blood vessel, it may reach a temperature at which the blood denatures and coagulates. If the tissue is collagen, it may reach a temperature at which the collagen denatures and is destroyed. The body's natural immune system removes the destroyed tissue, starting a process to regenerate new tissue.

[0016] The electrical resistance of various tissues varies widely. Tissues in the body with relatively high resistance are bone, fat and the outer layer of the epidermis. Tissues with moderate resistance are connective tissue and the dermis. The tissue with the lowest resistance is the blood. When high frequency electricity is used in dermatological applications, it tends to follow the pathways of the blood vessels, avoiding the fatty tissues and connective tissues.

SUMMARY OF THE DESCRIPTION

[0017] There are many different embodiments of apparatuses and methods which are described below. The apparatuses are typically (but not necessarily) handheld devices which apply energy (e.g., coherent and/or incoherent light) from one or more sources in the handheld device. The device may include a negative

pressure conduit (e.g., a tube which couples the skin to a vacuum source/pump) which can be used to draw the skin into a region of the device. This will tend to stretch the skin and bring one or more targets (below the surface of the skin) closer to the surface so that these targets receive more incident energy as a result of being closer to the surface.

[0018] The device may also include a pixilated display for displaying information (e.g., skin temperature, elapsed treatment time, etc.). The device may also include sensors (e.g., skin color sensors, temperature sensors, motion sensors, vapor pressure sensors, material sensors, and/or capacitance sensors), and may also include an object which is used to mechanically push the skin (thereby providing a positive pressure to a portion of the skin). A device may have multiple, different sources of energy. The sources of energy may, for example, be different laser diodes which emit light of different wavelengths. A device may include a pressure conduit which creates a positive pressure (e.g., a pressure above ambient atmospheric pressure). This pressure conduit may, in certain embodiments, be the same conduit which provides a vacuum or it may be a different, separate conduit.

[0019] It will be appreciated that there are various alternative apparatuses which can have various combinations of the different features. For example, a handheld device may include the following features and/or a subset of these features: a negative pressure conduit (e.g., a tube coupled to a vacuum pump to generate a vacuum over a treatment area); a positive pressure conduit (e.g., a tube coupled to an air pump to allow the device to be released after a treatment and/or to “float” over the skin as the device is moved into a position over the skin); and an object to mechanically push the skin (e.g., a piston and/or plunger to push blood away from a treatment area just before exposing the area to energy); and multiple, different sources of energy (e.g., several light sources of different wavelengths and/or other properties); and one or more sensors (e.g., one or more skin color sensors and/or skin temperature sensors to provide feedback to a user, and/or to

an automatically controlled processing system before, during, and/or after a treatment; and a pixilated display having rows and columns of pixels on a portion of the device (e.g., a backlit liquid crystal display device which displays skin temperature and other information); and two different vacuum regions, a first vacuum region creating a vacuum in a border region of external biological tissue which surrounds a desired treatment area of external biological tissue and a second vacuum region which applies a vacuum to the desired treatment area after a vacuum has been applied to the border region; and other aspects and/or features described herein.

[0020] In one aspect a device includes a cavity which, when pressed against a biological external tissue forms a chamber against (or encompassing) the biological external tissue. In one aspect, a device may include a material in the chamber to vaporize at the pressure below atmospheric pressure to prevent burning the biological external tissue. The material may be water, ethyl alcohol, and/or any material that has a vapor pressure below atmospheric pressure.

[0021] Various methods of operating these apparatuses are also described. In one aspect, a method to treat a target includes furnishing a material (e.g., a liquid) to a biological external tissue inside an inner chamber, applying an energy to the biological external tissue inside the inner chamber, and causing the material to evaporate. In one aspect the material evaporates during application of the energy to treat the target. In one aspect, an outer portion of a device and an inner chamber of the device are applied to the biological external tissue such that the outer portion contacts the biological external tissue and the inner chamber occupies a space above a portion of the biological external tissue having the target. In one aspect, pressure within the inner chamber may be reduced to a first pressure that is below atmospheric pressure to bring at least some of the biological external tissue into the inner chamber and to also cause the material to evaporate, thereby providing evaporative cooling which may occur before, during or after the application of the energy to treat the target. In another aspect, the

biological external tissue that is outside the device may be prevented from stretching. Other exemplary aspects are also described.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The present invention is illustrated by way of example and not limitation in the Figures of the accompanying drawings in which like references indicate similar elements.

[0023] Figure 1a is a diagram showing the various layers of the skin and potential targets for photo therapy and/or electrical therapy, according to one embodiment.

[0024] Figure 1b is a chart showing the percentage of incident energy transmitted through the epidermis for three different skin types, according to one embodiment.

[0025] Figure 1c is a chart showing the percentage of incident energy transmitted through the dermal plexus for two different levels of blood concentration (shown as ratios of blood to the rest of the tissue in a given volume), according to one embodiment.

[0026] Figure 2a is a process flow diagram showing a method of applying positive pressure and negative pressure to biological external tissue having a target, according to one embodiment.

[0027] Figure 2b is a process flow diagram showing a method for applying negative pressure to biological external tissue having a target, according to one embodiment.

[0028] Figure 2c is a process flow diagram showing a method for applying a sequence of positive pressure, negative pressure, and positive pressure to biological external tissue having a target, according to one embodiment.

[0029] Figure 3 is a cross-sectional view of a device 300 having multiple light sources 303a, 303b, and 303c, and a pressure conduit 304, according to one embodiment.

[0030] Figure 4 is a cross-sectional view of a device 400 having a pair of electrodes 403a and 403b, an object 401, a pressure conduit 404 and an electric current passing through biological external tissue 302, according to one embodiment.

[0031] Figure 5 is a cross-sectional view of a device 500 having multiple energy sources 503a-c, an object 401 and a pressure conduit 504, according to one embodiment.

[0032] Figure 6 is a cross-sectional view of a device 600 having multiple energy sources 503a-c, a pressure conduit 504, and a skin temperature sensor 601, according to one embodiment.

[0033] Figure 7 is a cross-sectional view of a device 700 having multiple energy sources 503a-c, a pressure conduit 504, a membrane 301, electrodes 503d and 503e, and a skin color sensor 701, according to one embodiment.

[0034] Figure 8 is an exemplary display 800 on a handheld device according to certain embodiments of the invention.

[0035] Figure 9 is a handheld device 900 with a display element 901 that displays at least one parameter with respect to a treatment of the biological external tissue 302, according to one embodiment.

[0036] Figure 10 is a cross-sectional view of a device 1000 having multiple energy sources 503a-503e that are not exposed to any pressure, and a pressure conduit 1004, according to one embodiment.

[0037] Figure 11 is a cross-sectional view of a device 1100 having a body that is applied to biological external tissue 302 and multiple vacuum chambers as shown in A and B on Figure 11, according to one embodiment.

[0038] Figure 12 is a cross-sectional view of an apparatus 1200 that attaches to an existing device 1201 to apply energy to biological external tissue 302 through energy sources 503a-c.

[0039] Figure 13 is an electrical schematic of a handheld device according to one exemplary embodiment.

[0040] Figure 14A-F are graphical process flows of a device to treat biological external tissue using a liquid and/or other material to cool the biological external tissue before and/or during application of an energy, according to one embodiment.

[0041] Figure 15 is a cross-sectional view of a device 1500 having a body that is applied to biological external tissue 302, the device 1500 having multiple vacuum chambers and a material conduit thru which a material is applied to the biological external tissue, according to one embodiment.

[0042] Figure 16 is an operation flow of reducing pressure of an inner chamber and applying a material to the biological external tissue, according to one embodiment.

[0043] Figure 17 is an operation flow of forming a vacuum seal between a device and a biological external tissue, and applying a material to the biological external tissue within a chamber formed above the biological external tissue, according to one embodiment.

[0044] Figure 18 is an operation flow of coating a liquid on an area of biological external tissue, forming a pressure equal to or lower than a vapor pressure of the liquid, and applying an energy to a target before the blood concentration in the biological external tissue returns to at least a normal state, according to one embodiment.

[0045] Figure 19 is an operation flow of depositing a material on an area of a biological external tissue having a target, applying a device to the area, and bringing the biological external tissue into contact with a protruding object of the device that is above the area.

[0046] Figure 20 is an operation flow of reducing temperature of an area of a biological external tissue having a target by depositing a material on the area, applying a negative pressure to bring the biological external tissue into contact with the device, and applying an energy to the target before the blood

concentration in the area returns to at least a normal state, according to one embodiment.

[0047] Figure 21 is a graph illustrating the vaporization pressure in PSI of ethyl alcohol and water as a function of temperature in Celsius, according to one embodiment.

[0048] Figure 22 is a graph illustrating the time in seconds to burn biological external tissue, according to one embodiment.

[0049] Figure 23 is a three-dimensional, cut-away view of a device to treat biological external tissue according to one embodiment.

[0050] Figure 24 is a three-dimensional view of a device having an inner chamber and an outer portion to treat biological external tissue according to one embodiment.

DETAILED DESCRIPTION

[0051] Prior to describing specific devices which are embodiments of the invention, several methods which are also embodiments of the invention will be described. Figure 2a is a process flow diagram showing a method of applying positive pressure and negative pressure to biological external tissue having a target. According to one embodiment of the invention, when the negative pressure is applied to the skin and the volume of biological external tissue is pulled into the device, blood is pulled into the dermal plexus and the dermis. In operation 201 a device is applied to biological external tissue having a target. The device may be, for example, the device 400 shown in Figure 4. According to one embodiment of the invention, the biological external tissue is dermalogical tissue and the device is applied by pressing the device against such tissue to create a sealed region between the device and such tissue. The target is skin lesions in one embodiment of the invention. In another embodiment of the invention, the target is melanin, blood, tattoo ink, and/or collagen. However, the invention is not so limited. The target can alternatively be any biological external

tissue requiring treatment by an energy source. In operation 202a of Figure 2a, a positive pressure is applied to the biological external tissue.

[0052] According to one embodiment of the invention, the positive pressure is applied using an object which protrudes from a surface of a body of the device (such as object 401) which surface faces the area to be treated. According to another embodiment of the invention, the positive pressure is a gas such as a cooling gas, which is applied to the biological external tissue. In operation 203 of Figure 2a, a negative pressure is applied to the biological external tissue.

According to one embodiment of the invention, the negative pressure is a vacuum (e.g., a pressure which is less than or substantially less than atmospheric pressure, such as 400 torr). In operation 204 of Figure 2a, energy is applied to the target inside the biological external tissue. The energy is incoherent light, coherent light, radio frequency, and/or ultrasound, according to various embodiments of the invention. However, the invention is not so limited. The energy source may be a combination of multiple energies such as a radio frequency and a coherent light in some embodiments of the invention. In another embodiment of this invention, pressurized gas is used to force the blood out of the dermal plexus. The positive pressure applied in operation 202a tends to push blood out of the treatment area, thereby reducing the amount of energy absorption by the blood in the treatment area. This pushing of blood normally occurs just before the application of energy to the treatment area.

[0053] Figure 2b is a process flow diagram showing a method for applying negative pressure to biological external tissue having a target. In operation 201 of Figure 2b, a device (such as, for example, the device 300 shown in Figure 3) is applied to biological external tissue having a target; operation 201 of Figure 2b may be similar to operation 201 of Figure 2a. In operation 203 of Figure 2b, a negative pressure is applied to the biological external tissue. In operation 204 of Figure 2b, energy is applied to the target, which may be energy as described with

reference to Figure 2a. In Figure 2b, no positive pressure is applied to the biological external tissue prior to the negative pressure being applied.

[0054] Figure 2c is a process flow diagram showing a method for applying a sequence of positive pressure, negative pressure, and positive pressure to biological external tissue having a target. In operation 201 of Figure 2c, a device (such as, for example, the device 400 shown in Figure 4) is applied to biological external tissue having a target, as described with reference to Figure 2a. In operation 202c, a first positive pressure is applied to the biological external tissue. As described with reference to the method of Figure 2a, the positive pressure may be a cooling gas and/or an object. In operation 203 of Figure 2c, a negative pressure is applied to the biological external tissue; this is similar to operation 203 of Figure 2a. In operation 204 of Figure 2c, energy is applied to the target; this is similar to operation 204 of Figure 2a. In operation 202d, a second positive pressure is applied on the biological external tissue. This second positive pressure may be a gas which pushes the device off the biological external tissue, thereby making it easier to release and move the device from the treatment area to the next treatment area. According to some embodiments of the invention, the first positive pressure and the second positive pressure originate from the same pressure source. In some embodiments of the method of Figure 2c, operation 202c may overlap in time with operation 203 or the sequence may be reversed. Normally, the negative pressure is applied while the energy is applied so operations 203 and 204 overlap substantially in time.

[0055] In alternate embodiments of the invention, the first positive pressure and the second positive pressure are different positively applied pressures on the biological external tissue. For example, the first positive pressure is applied by a mechanical object (e.g., object 401) while the second positive pressure is applied by pumping a gas (e.g., air) into the recess between the device and the skin and/or other biological external tissue. In some embodiments of the process flows of the invention, as shown in Figures 2a, 2b and 2c, the number of uses of the device is

kept track of to determine usage patterns of the device. The energy used in the methods of Figures 2a, 2b, and 2c, may originate from a source that is not exposed to any negative and/or positive pressure according to at least one embodiment of the invention. In another embodiment of the invention, generating a peripheral vacuum seal to keep the device on the area of biological external tissue can also be performed and is described further below.

[0056] The energy may be an electrical current that is applied to the area of biological external tissue before the blood concentration in the area returns to a normal state (or higher than normal state), according to some embodiments of the invention. Furthermore, measuring color of the biological external tissue can alternatively be performed in some embodiments of the methods shown in Figures 2a, 2b and 2c. Similarly, measuring temperature of the biological external tissue may also be performed in some embodiments of the methods shown in Figure 2a, 2b and 2c. The device may display at least one measurement of a sensor on the device in some embodiments of the invention. According to one embodiment of the invention, temperature can be measured by monitoring the change in electrical impedance of the treatment volume. The device may be a handheld device in some embodiments of the invention. In other embodiments, a power source may provide power to the device and generate the positive pressure and/or negative pressure through a pressure source connected to the device through a cable element.

[0057] In some embodiments of the invention, the power level (e.g., strength) of the energy may be automatically regulated by a controller. The controller may also perform other functions. The controller may, for example, contain a timer that is monitoring the elapsed time since a positive pressure is applied to the treatment volume, according to one embodiment of the invention. The result of a large elapsed time is a pool of blood that returns to the surface of biological external tissue such as skin. All skin types including type VI assume a more reddish appearance. The presence of this pool of blood significantly impacts the

therapy. The blood absorbs much of the light energy particularly if the energy is in the visible portion of the spectrum. If the target such as a hair follicle, a tattoo, and/or collagen is deeper in the body than the pool of blood, the therapy is unsuccessful as the majority of the treatment energy is absorbed in the pool of blood before reaching the intended target.

[0058] Based upon clinical measurements, the blood volume in the dermal plexus and dermis is reduced for a period time before it refills the capillaries and other vessels in these regions. This period of time is on the order of 100msec, but varies from individual to individual. By monitoring the elapsed time since application of a positive pressure, the treatment (e.g., application of energy) can be performed in this time period before the blood refills this tissue.

[0059] After the controller determines the tissue is in place and, if required, the elapsed time is less than the blood refill time, the therapy is applied to the volume of skin contained inside the device. If photo-therapy is used, an intense light such as from a laser and/or a flash lamp is directed onto the treatment area of the biological external tissue. If rf therapy is used, an electrical voltage is applied to the electrodes and current is passed through the volume of tissue between the electrodes. Once the therapy is completed, the negative pressure is removed and the skin returns to its normal state.

[0060] A controller may function in the following manner in the case of a device 400 of Figure 4. This particular device 400 may provide a positive pressure whenever it is being moved from one treatment area to another treatment area. As noted above, the device typically has a recessed area which faces the skin and which is enclosed by the device and the skin when the device is pressed against the skin. The positive pressure (e.g., from a gas) is typically emitted from the recessed area, and this positive pressure will cause a pressure buildup when the device is pressed against the skin to create a seal between the device and the skin. When the device is being moved, there is no seal and thus no pressure buildup between the skin and the device. When it is pressed against the skin, the positive

pressure (e.g., a pressure greater than atmospheric pressure) between the device and the skin will be measured by a pressure sensor, and this indicates to the controller that the movement of the device has stopped and that the user has positioned the device over a desired treatment area. At this point, the controller may be programmed as built to automatically shut off the positive pressure and begin drawing a vacuum against the skin to lock the device in place over the desired treatment area. Alternatively, the controller may be programmed and/or built to merely stop the positive pressure (e.g., shut off the flow of a gas into the recess which creates the positive pressure) but not start a vacuum until the user of the device switches a vacuum on. This alternative implementation gives the user a chance to adjust the positioning before turning the vacuum on by a command from the user.

[0061] The biological external tissue that is outside of the device may be prevented from stretching in some embodiments of the methods shown in Figures 2a, 2b and 2c. A technique for preventing this stretching is described below.

[0062] Figure 3 shows, in cross-sectional view, a device 300 having multiple light sources 303a, 303b, and 303c, and a pressure conduit 304. The light sources are contained within a housing and/or body which also includes a cover (which is transparent in the case of light sources) and which separates the light sources from any vacuum generated between the skin and the device). The cover is disposed between the membrane 301 and the light sources 303a-303c. A handle which is coupled to the body may also be included so that a user of the device can easily hold and move the device over a patient's skin and/or other biological external tissue.

[0063] A recess and/or void exists between the membrane 301, which faces the biological external tissue 302, and the biological external tissue 302 shown in Figure 3. Pressure conduit 304 generates a negative vacuum through membrane 301 to bring the biological external tissue 302 into the recess and toward the membrane 301. Membrane 301 can be used to collect dead skin, according to

one embodiment of the invention. The membrane 301 is coupled to the conduit 304 to receive the suction from a vacuum pump (not shown) which is coupled to the conduit 304. Light sources 303a, 303b and 303c in Figure 3 are connected to an energy source that is not shown on the figure, according to one embodiment of the invention. This energy source is not exposed to any pressure through the pressure conduit 304, according to one embodiment of the invention. These light sources are shielded from any negative (or positive) pressure by the cover which is optically transparent in the case where the energy sources provide visible light. It will be appreciated that the light sources may alternatively be other types of energy sources (e.g., microwave radio frequency energy) which may not require an optically transparent cover.

[0064] The energy applied to biological external tissue 302 through device 300 is transferred through light sources 303a, 303b and 303c. The light sources 303a, 303b, and 303c may include, for example, light emitting diode (LED) lasers of different wavelengths, thus providing different energy sources, due to the different wavelengths, in the body of the device. Each light source (e.g., source 303a and/or 303b and/or 303c) may be a panel of multiple LED lasers which may be the same type of LED (to produce the same wavelength) and/or may be a panel of multiple LED lasers which may be a different type of LED (to produce different wavelengths). The three panels shown in Figure 3 (light sources 303a, 303b, and 303c) are arranged within the body of device 300 to provide a spatially uniform lighting at the target so that the intensity of light, at any point over an area which includes the target, is substantially the same. It can be seen from Figure 3 that the panels (e.g., light source 303a) transmit light directly to the target without any intervening optical fibers and/or waveguides.

[0065] This energy for device 300 can be incoherent light, coherent light, and/or alternatively non-visible light and/or electromagnetic radiation in the range of a radio frequency spectrum, and/or ultrasound, according to various embodiments of the invention. The energy source for the device 300 may be a flash lamp, arc

lamp, high frequency electrical energy, rf energy, an LED and/or a Direct Current electrical energy, according to various embodiments of the invention. However, the invention is not so limited. The present invention can be multiple combinations of different energies which are provided by energy sources in the body of the device 300. The device 300 may also be connected to a pressure source in the device 300 for providing power to the device 300 and generating pressure through a pressure conduit 304 in one embodiment of the invention. In another embodiment of the invention, the device 300 may be a handheld device that is connected to the pressure source (through a cable element), where the pressure source and power source is separate from the handheld device. In addition, a controller on and/or near device 300 may control the strength of the energy applied through the light source 303a, 303b and/or 303c. According to one embodiment of the invention, there are three light sources, however, any number of light sources is contemplated by the present invention. In one embodiment of the invention, a tapered outer wall on the periphery of device 300 prevents the biological external tissue 302 that is outside the device 300 from stretching.

[0066] Stretching the skin (1) reduces the concentration of melanin in the epidermis, (2) reduces scattering in both the epidermis and the dermis, and (3) moves the treatment target closer to the surface. Vacuum provides an excellent mechanism for stretching the skin. By sealing on an area of skin, and generating a vacuum, the skin is drawn and stretched much more than can be done manually.

[0067] Figure 4 shows, in cross-sectional view, shows a device 400 having a body which is coupled to a pair of electrodes 403a and 403b, and the body supports an object 401 which protrudes into a recess of the body. A pressure conduit 404, which is coupled to the body, generates a positive and/or negative pressure on biological external tissue 302. The object 401 is designed to be brought into contact with biological external tissue 302 either before and/or while a negative pressure through pressure conduit 404 is applied, thereby drawing the

skin into the recess and into contact with the object. The object is used for pressing onto the biological external tissue 302 and forcing the blood out of the dermal plexus, according to one embodiment of the invention. The object 401 may be stationary relative to the body and/or it may move, like a plunger and/or piston, down from the body and toward the skin. A stationary object is simpler and easier to build but will require that the vacuum draw the skin sufficiently into contact with the object. The moving object can provide more force and the recess can be larger. The object 401 may be transparent in the optically visible spectrum, thereby allowing light to pass through it in those embodiments (such as, e.g., the device of Figure 5) which include light sources which emit light that must pass through the object to reach the target.

[0068] According to some embodiments of the invention, pressure conduit 404 generates a positive pressure that is a gas, which may be a cooling gas.

According to one embodiment of the invention, the gas that is used to apply pressure to the biological external tissue 302 to force the blood out of the dermal plexus and the dermis may also be used to assist in releasing the device 400 from the biological external tissue 302. In another embodiment of the invention, the cooling gas is applied before applying an electric current 405 through the biological external tissue 302 through electrodes 403a and 403b. In another embodiment of the invention, the pressure conduit 404 generates a peripheral vacuum seal to hold the device 400 on biological external tissue prior to generating a vacuum in the recess of the body.

[0069] The object 401 that applies pressure to the biological external tissue 302 to force the blood out of the dermal plexus and the dermis may be cooled to a temperature lower than the epidermis, according to one embodiment of the invention. Without cooling, the normal epidermis starts at a temperature between 31 degrees Celsius and 33 degrees Celsius, according to one embodiment of the invention. During treatment, it will rise in temperature and may reach a temperature at which burning occurs. If the epidermis starts at a temperature

lower than normal, it can change in temperature during treatment more than uncooled skin before it reaches a temperature at which burning occurs.

[0070] The gas that is used to apply pressure to the biological external tissue 302 to force the blood out of the dermal plexus and the dermis may be cooled to a temperature lower than the epidermis, according to one embodiment of the invention. The benefit of this cooling with pressurized gas is the same as the benefit obtained with a cool object 401. The object 401 that applies pressure to the biological external tissue 302 to force the blood out of the dermal plexus and the dermis may contain an optical coating to control the wavelengths of light that are used in the treatment, according to another embodiment of the invention. In some embodiments of the invention, the object 401 that applies pressure to the skin to force the blood out of the dermal plexus and the dermis may contain an optical coating to control the energy of the light that is used in the treatment. According to one embodiment of the invention, DC or AC or capacitance electrical sensors 403a and 403b are used to determine if the biological external tissue 302 is properly positioned in the device 400.

[0071] The device as shown in Figure 4 can include various sensors such as skin color sensors, temperature sensors, and capacitance sensors on the device in some embodiments of the invention. Furthermore, the device shown in Figure 4 may have a tapered outer wall on the periphery of the device that prevents the biological external tissue 302 that is outside of the device 400 from stretching, similarly to as described with reference to Figure 3. Other features from other embodiments described herein may also be added to the device as shown in Figure 4.

[0072] The electrodes 403a and 403b in Figure 4 can serve two purposes. One purpose is for applying rf treatment energy according to one embodiment of the invention. The second purpose is as an electrical sensor, according to a different embodiment of the invention. An AC or DC voltage is applied to at least two of the electrical sensors in other embodiments of the invention. When the biological

external tissue 302 contacts two of the electrical sensors 403a and 403b, an electrical current 405 passes between the two electrodes 403a and 403b. When a sensor within device 400 detects the current 405, it signals a controller within and/or outside device 400. The controller interprets this signal to mean that the biological external tissue 302 is properly positioned according to one embodiment of the invention. This can serve as a secondary skin detection system for added safety, according to at least one embodiment of the invention.

[0073] Figure 5 shows in cross-sectional view, a device 500 having multiple energy sources 503a-c, an object 401 and a pressure conduit 504. In a typical treatment, the device 500 is pressed against the skin, and the skin is drawn into the recess of the body of device 500 as shown in Figure 5. According to one embodiment of the invention, the device 500 generates a positive pressure against the skin (through the object 401) followed by a negative pressure (through a vacuum pump coupled through a valve to conduit 504), and then again a positive pressure (from an air pump coupled, through a valve, to conduit 504) to be applied to biological external tissue 302 through pressure conduit 504. The positive pressure from the object 401 may be done concurrently with the generation of a vacuum (negative pressure) in the recess. This sequence helps certain treatment procedures of biological external tissue 302 requiring blood within the biological external tissue 302 to be pushed away prior to the treatment. Figure 5 differs from Figure 3 and Figure 4 in that the device shown in Figure 5 can generate both an electric current through electrodes 503d and 503e (to either sense the device's contact with the skin and/or to deliver electrical energy as a treatment) and can apply energy through sources 503a, 503b and 503c on device 500. The energy sources 503a, 503b, and 503c may be similar to the sources 303a, 303b, and 303c. However, the energy through energy sensors 503a, 503b and 503c is not limited to light, according to one embodiment of the invention as shown in Figure 5. The pressure conduit 504 generates at one point in time in a treatment sequence, a positive pressure comprising a gas in an area of the

biological external tissue 302 in Figure 5. However, the pressure conduit 504 can alternatively generate negative pressure at a different time in the sequence by switching a valve which connects the conduit to either an air pump and/or a vacuum pump. Other features (such as, e.g., skin color sensors, a display, etc.) from other embodiments described herein may also be implemented on the device as shown in Figure 5.

[0074] In Figure 5, a high frequency rf electrical current 405 enters the body from one electrode 503d, passes through a layer of biological external tissue 302 and exits the body at a different electrode 503e. Figure 5 shows a potential pathway through the biological external tissue 302 for this current 405. As the current 405 passes through the body, it tracks a path through the least resistive tissues. Blood is the most conductive biological entity and hence the rf electricity tends to track the blood vessels. This is fine if the target for the rf is the blood, but if the target is the adjacent tissue such as collagen, the presence of the blood can defeat the intended therapy.

[0075] Figure 6 shows in cross-sectional view, a device 600 having multiple energy sources 503a-c, a pressure conduit 504, and a skin temperature sensor 601. The skin temperature sensor 601, as shown in Figure 6, is a capacitance sensor. It may be placed on the membrane 301 rather than within the body of the device. In one alternative embodiment of the device 600, an object 401 may also be used, as shown with reference to Figure 4. Furthermore, other features from other embodiments described herein may be added to the device 600 shown in Figure 6. The skin temperature sensor 601, as shown on device 600 in Figure 6, is used to measure the temperature of the biological external tissue 302 to prevent burning when applying energy through one or more of energy sources 503a-c to biological external tissue 302.

[0076] According to one embodiment, the skin temperature sensor 601 is a non-contact skin temperature sensor that monitors the infrared light emitted from the surface of the biological external tissue 302 and translates this into a surface

temperature. The information from the skin temperature sensor 601 is sent to a controller which is within the body of the device 600 in certain embodiments of the invention. The controller is a micro controller and/or microprocessor that interprets the skin temperature, and if the temperature has reached a dangerous level, the micro controller terminates the application of energy in one embodiment of the invention. According to another embodiment of the invention, the controller is a software controlled micro controller and/or microprocessor.

[0077] Figure 7 shows in cross-sectional view, a device 700 having multiple energy sources 503a-c, a pressure conduit 504, a membrane 301, electrodes 503d and 503e, and a skin color sensor 701. Figure 7 differs from Figure 6 in that it does not have a skin temperature sensor 601, but rather has a skin color sensor 701. The skin color sensor 701 is used to measure the level of energy that needs to be applied to biological external tissue 302 based upon the color of the skin and corresponding melanin and blood levels within biological external tissue 302. Other features (such as, e.g., an object 401, etc.) from other embodiments described herein, may be added to the device shown in Figure 7.

[0078] The skin color sensor 701 consists of a light source and a photodiode. By shining the light source on the surface of the biological external tissue 302 and reading its reflection with the photodiode, the skin color can be determined. The light source may be adjacent to the photodiode (as shown), or it may be separated from it. Determining the skin color prior to treatment is important. Even with stretching, dark skin is still more susceptible to burning than lighter skin. Consequently the treatment energy may be adjusted based upon the readings of the skin color sensor. For darker skin, the treatment energy is lowered. For lighter skin, the treatment energy is raised.

[0079] Clinical tests of device 700 on lighter skin types shows that the skin color sensor (4) can also be used to detect the absence of the blood and further detect the refill of the vessels in the dermal plexus and dermis. Prior to stretching the

biological external tissue 302, such as skin, into the device 700, the skin color is measured. As the skin is stretched and the blood is removed from the dermal plexus, the reflected light detected by the photo diode increases due to less absorption by the blood. As the dermal plexus refills, the reflected signal decreases due to increase absorption by the blood. The skin color detection device monitors this change and notifies a control system within and/or outside the device 700, according to certain embodiments of the invention.

[0080] Stretching the epidermis reduces the concentration of melanin. To understand this phenomenon, consider a colored balloon. The pigmentation in the balloon gives it its color. The melanin pigmentation in our skin gives us our color. When a colored balloon is deflated, it is difficult or impossible to see through it. It is opaque. As the balloon is inflated, it becomes more transparent. The elastic portion of the balloon stretches. The inelastic portion, such as the pigment, does not stretch. Its concentration is reduced and the balloon becomes more transparent. The same happens in our skin. The melanin is less elastic than the interstitial components. These tissues stretch while the melanin does not. As the concentration of melanin drops, the skin becomes whiter. In fact, by stretching the skin of a dark individual, the skin becomes quite pink as the underlying vascular system becomes exposed.

[0081] The second advantage of stretching the skin prior to and during treatment with intense light sources is the reduction in scattering. When light enters human tissue, it is immediately scattered in all directions by the collagen, fibrous tissue and other intercellular constituents. Much of this light is scattered back to the surface and out of the body. Much is scattered sideways and thereby reduces the energy density as the cross-section of the intense light source increases. The level of scattering is directly proportional to the concentration and orientation of the intercellular material. Stretching the skin reduces the concentration of these materials in direct proportion to the level of stretching. The corresponding scattering is subsequently reduced as well.

[0082] As described above, the two advantages to stretching the skin is reduced absorption by melanin and reduced scattering. The third advantage is that the treatment target moves closer to the surface. Stretching the skin reduces its thickness. One can see this by taking a rubber band and measuring its thickness. Then stretch the rubber band and measure its thickness a second time. The rubber band is thinner. The same effect occurs with the outer layers of the skin. The epidermis becomes thinner. The dermal plexus becomes thinner. Even the dermis becomes thinner. The target however, remains in the dermis and is now closer to the surface and thus more energy can reach it.

[0083] Figure 8 shows an exemplary display which may be disposed on a surface of a handheld device, such as any of the devices shown in Figures 3-7 and 9-11. Figure 9 shows a perspective view of a handheld device 900 with a display on a surface of the device. The device of Figure 9 may include the various features described herein, such as multiple energy sources, an object which pushes blood out of the treatment area, one or more pressure conduits, etc. The device 900 includes a pixilated display with multiple rows and columns of pixels on the display 901. An example of the content of such a display is shown in Figure 8 which shows a display 800 which indicates the status 801 of the device (e.g., "Standby" or "On" or "Treating"), the power status 802 of the device (e.g., Low or Medium or High along with a bar graph which indicates the power status), the vacuum status 803 of the device (e.g., pneumatic level is "Low" or "High"), the skin's temperature 804 (e.g., 42°C), the skin's color 805 (e.g., 4) and the patient's pulse count 806 (e.g., 76). The display 800, being on the handheld, is easier for an operator (e.g., physician) to see while doing a treatment because the operator can look at the treatment site while operating the device and still be able to see both the site and the display (rather than having to look at a console which has a display and which is separate from the handheld device. The display 901 may be a liquid crystal display (LCD) and/or an LED display which is controlled by a display controller which updates the display's pixels to reflect new information.

The device 900 includes a power adjustment control 904 which can be used to control the amount of energy that is applied to the biological external tissue (e.g., to adjusting the intensity of the light from light sources). The device 900 also includes a pneumatic adjustment control 903 to control the strength of a vacuum that is applied through a vacuum pump (not shown) through the device 900 (e.g., (e.g., a pressure which is less than or substantially less than atmospheric pressure, such as 400 torr). Furthermore, the device 900 includes a cable 905 that delivers power and pressures to operate device 900 (e.g., the cable 905 is connected on the other end to a wall power outlet, and/or a standalone central control station); a vacuum through device 900 to be applied to the biological external tissue in front of the disposable tip 902 (e.g., the vacuum may be delivered through conduit 905 along with power by maintaining a separate chamber that separately carries a negative pressure through device 900); a positive pressure to press down on biological external tissue (e.g., carried through a separate chamber than the one that carries the vacuum and power); and the cable 905 may optionally include various electrical wires that deliver signals to and from various sensors (e.g., sensors on the device 900 may include skin temperature sensors, skin color sensors, and capacitance sensors, etc.) on device 900 to a standalone central control station (not shown) in addition to (or rather than) the hand piece display 901. In one embodiment, the standalone central control station may be a computer that has a printer and/or storage device(s) for recording data from the sensors on device 900. The disposable tip 902 on device 900 may be a disposable membrane 301 and/or may be custom designed to fit a particular type of biological external tissue or size of biological external tissue (e.g., the disposable tip 902 may be different for large areas of skin verses small areas of skin, and may be shaped differently to treat areas of biological external tissue that is not purely flat because of contours created by skeletal structures and/or because of hair follicles). The handle 906 of device 900 may be designed to fit a particular size of hand or may have groves to fit a particular hand size in some

embodiments. In addition, in other embodiments the handle 906 may be of variable size (e.g., to fit larger and smaller hands, or to reach into areas of biological external tissue that are otherwise difficult to reach). The handle 906 may be removable from the device 900 head (e.g., the head might be the handpiece display 906 and disposable tip 902 together) in one embodiment to allow a user of device 900 to quickly put on different types of sensors, display 901 variations, and disposable tip elements 902.

[0084] Figure 10 shows a device 1000 having multiple energy sources 503a-503e that are not exposed to any pressure, and a pressure conduit 1004. Figure 10 differs from Figure 3 in that the device shown in Figure 10 includes multiple energy sources such as electrodes 1003d and 1003e, while the device shown in Figure 3 is limited to light based energy only. In one embodiment of the present invention, the pressure conduit 1004 in Figure 10 generates a negative pressure.

[0085] Figure 11 shows a device 1100 having a body that is applied to biological external tissue 302 and multiple vacuum chambers shown as A and B on Figure 11. The device 1100 in Figure 11 applies two vacuum pressures at different times to biological external tissue 302. In other embodiments of the invention as shown in Figure 11, there are any number of vacuum chambers A, B on device 1100. One pressure A is generated at the periphery of device 1100 through the pressure conduits 1004 and 1003. A second pressure is generated as shown in B through the pressure conduit 1103. The device 1100 includes multiple energy sources 503a, 503b, and 503c and electrodes 503d and 503e. The membrane 301 has two portions: an interior portion 1101A which generates an interior vacuum in the recess 1106 of the body of device 1100 and a peripheral border portion 1101B which generates a peripheral vacuum seal between the flat surface of the periphery of the device 1100 and the skin. A valve 1107 couples the two vacuum chambers together and may be manually controlled by an operator and/or automatically controlled by a micro controller (e.g., micro controller 1303 in the handheld device). Initially, the valve 1107 is set so that a vacuum is generated in

only the peripheral border of the device; the peripheral border may be a rectangular frame (resembling a picture frame) or other shapes. This clamps the device to the skin without creating a vacuum in the recess 1106. Then the valve 1107 is switched so that a vacuum is generated in both the peripheral border and the recess 1106 of the device. In an alternative embodiment, the valve may be positioned at the junction between the portion 1101A and 1101B and no separate conduit 1103 is required; in this case the valve is switched open to extend a vacuum from the peripheral border region to the interior region. The advantage provided by a device such as device 1100 is that the skin within the recess can be stretched even more than skin within devices such as device 300 or 400 because less skin outside of device 1100 will be pulled in by the vacuum within the recess. The skin in the peripheral border region is clamped into a relatively fixed position before the skin within the recess is exposed to a vacuum, which tends to prevent skin from being pulled into device 1100 from outside of the device 1100. One or more features (such as, e.g., an object 401, skin color sensors, pressure sensors, a display on the handheld, etc.) from other embodiments described herein may be added to the device 1100 according to certain implementations of the invention.

[0086] Figure 12 shows a device that is an apparatus 1200 that attaches to an existing device 1201 to apply energy to biological external tissue 302 through energy sources 503a-c. The apparatus shown in Figure 12 is an embodiment of the invention that is an add-on to existing device 1201. The apparatus 1200 adds one or more features as described with reference to Figures 1-11 in various embodiments of the invention.

[0087] Figure 13 shows an electric architecture for a handheld device such as device 900. The device 1301 shown in Figure 13 includes an LCD display 1308 having multiple rows and columns of pixels. The output of display may be the same as or similar to the output of display 800. The display 1308 is coupled to a programmable or programmed micro controller 1303 through a display controller

1304; it will be appreciated that the display controller 1304 may be eliminated if the micro controller performs the display updating functions of the display controller. The micro controller 1303 is coupled to sensors 1305 and to energy sources 1307 through a bus 1306. The sensors 1305 may be electrical skin contact sensors (such as, e.g., electrodes 503d and 503e), or pressure sensors which detect a pressure above or below atmospheric pressure, and/or skin temperature sensors, and/or skin color sensors and/or a combination of these (and other) sensors. The energy sources 1307 may be multiple light sources and/or radio frequency electrical electrodes and/or other types of energy sources described herein and/or a combination of these sources. The device 1301 also includes a cable 1309, which is similar to cable 905 (attached to handle 906) of the device 900 of Figure 9. The cable provides power to the handheld from a separate power supply (which may be bulky and thus not practical to hold in a hand), and the cable also provides vacuum and air pressures from a separate (potentially bulky) vacuum pump and air pump. The device 900 also includes manual controls such as a pneumatic adjustment control 903 (allowing the vacuum to be adjusted) and a power adjustment control 904 (allowing the power of a treatment to be adjusted manually by an operator). The device 900 also includes a disposable tip 902 which may be a detachable membrane such as membrane 301 which attaches to the treatment face of the body of the device 900.

[0088] The micro controller 1303 may be programmed to operate the device in one or more of the methods described herein. For example, the micro controller 1303 may receive signals from a skin color sensor 1305 which causes the micro controller 1303 to automatically adjust (without any user input and/or intervention) the power level of the energy sources; the handheld display can then be updated to show that the power level has been changed (and this may be noticed by the operator who can override the changed power setting). The skin color sensor(s) may also be used to detect the return of blood pushed away by an object protruding within the recess of the device; upon detecting this change in

skin color from signals from the skin color sensor, the micro controller shuts off the power to the energy sources in one embodiment of the invention, and another cycle (e.g., as shown in Figure 2a) may be performed to continue the treatment at the same treatment site. The micro controller 1303 may also receive signals from a skin temperature sensor 1305 which causes the micro controller 1303 to automatically adjust (without any user input and/or intervention) the power level of the energy sources; if, for example, the skin temperature becomes too hot, the micro controller may completely turn off the power to the energy sources in order to protect the patient's skin.

[0089] The micro controller 1303 may also receive signals from a pressure sensor which indicates that the device has been pressed against the skin at a desired treatment site, thereby creating a seal between the device and the skin; the resulting pressure change (due to this seal) in the recess is detected, and the micro controller begins, automatically, a desired treatment (at either predetermined settings previously entered by an operator and/or automatically based on skin color sensor signals and settings previously entered by an operator). In this case, the micro controller may cause an object (e.g., object 401) to press against the skin and cause the vacuum to be generated and then apply energy from the energy sources before the blood returns to the treatment. Pressing the object against the skin and generating a vacuum may be concurrent (completely overlapped in time) and/or partially overlapping in time and/or sequential with no overlap in time. The micro controller 1303 may use a timer to determine when the blood returns (to a normal concentration level after having been pushed away) and/or may use signals from a skin color sensor; the timer may be started upon pushing with the protruding object, and the elapsed time may be counted. In this way, the micro controller can assure that the energy is applied in the time period (e.g., 100m sec) before the blood returns to a normal concentration. If the object which pushes the blood away is moveable, the micro controller may control its movement.

[0090] Figures 14A-F are graphical process flows of a device to treat biological external tissue using a liquid and/or other material to cool the biological external tissue before and/or during application of an energy, according to one embodiment.

[0091] First, in Figure 14A, a device 1400 having an inner chamber 1402 may be applied to the biological external tissue 302. The pressure within the inner chamber 1402 of the biological external tissue is 1 ATM (e.g., atmospheric pressure) in Figure 14A. A target 1404 (e.g., a unwanted hair, a wrinkle, a skin blemishes, a tattoo, a vascular and pigmented lesion, etc.) may reside within the biological external tissue 302 directly below the inner chamber 1402. The target 1404 may be eradicated, reduced, and/or treated by the device 1400.

[0092] In one embodiment, at atmospheric pressure, a contact cooling of the biological external tissue 302 may be performed prior to or after placing the device 1400 on the biological external tissue 302 in Figure 14A. The contact cooling may be performed by placing a cold, optically transparent element (not shown) on the biological external tissue 302 prior to, during and after treatment (e.g., application of energy as later will be described in Figure 14E). The optically transparent element may cool the area to be treated (e.g., the biological external tissue 302 directly below the inner chamber 1402) to a temperature below normal body temperature (e.g. the normal body temperature of a human being, and/or other living being having biological external tissue 302). The temperature rise of the pre-cooled area of the biological external tissue 302 to a level where the biological external tissue 302 burns is more than for a non pre-cooled area. For example, if the goal is to always maintain a treated area of the biological external tissue 302 below 60C, the temperature of the treated area must rise from 33C to 60C or 27C if not pre-cooled. If pre-cooled to 10C, the area must rise 50C (e.g., from 10C to 60C). During the application of the energy, (e.g., as will be described in Figure 14E), the optically transparent element may remove heat from the treated area of the biological external tissue 302 faster than it is

removed without the cooling, thereby providing the biological external tissue 302 with additional protection from the heat caused by the treatment.

[0093] In another embodiment, at atmospheric pressure, a cryogen spray (e.g., a liquid, such as liquid nitrogen, that boils at a temperature below about 110 K (-160°C) and is used to obtain very low temperatures) may be used to pre-cool the biological external tissue 302 prior to placing the device 1400 on the biological external tissue 302 in Figure 14A. The cryogen spray (not shown) may cool an area of biological external tissue 302 to be treated by rapid evaporation of the cryogen. As with the contact cooling, temperature rise of the cryogen pre-cooled area to a level where the biological external tissue 302 burns are greater than for a non pre-cooled area. Furthermore, as with contact cooling, the cooling effect of the cryogen spray during the application of the energy, (e.g., as will be described in Figure 14E) provides some additional protection because the cryogen pre-cooled area may remove heat from the treated area of the biological external tissue 302 faster than it is removed without the pre-cooling.

[0094] Next, in Figure 14B, a seal 1406, (e.g., a vacuum seal), is formed between the device 1400 and the biological external tissue 302. In one embodiment, as shown in Figure 24, the seal 1406 may be formed within an outer portion 2402 of a device 2400. In yet another embodiment, as shown in Figure 11, the seal is generated at the periphery of the device 1100 through the pressure conduits 1004 and 1003. Referring back to Figure 14B, the seal 1406 may prevent the device 1400 from shifting above the target 1404 during an application of negative pressure, (as described in Figures 2a, 2b, and 2c, and as will be further discussed in Figure 14D), and/or shifting during the application of an of an energy (as described in Figures 2a, 2b, and 2c, and as will be further discussed in Figure 14E).

[0095] Then, in Figure 14C, a material 1408, (e.g., a liquid such as water and/or ethyl alcohol, and/or other solid, liquid and/or gas substance having desired properties), is applied to the biological external tissue 302. In one embodiment,

the material 1408 is applied through a conduit 1502 as shown on the device 1500 in Figure 15. The material 1408 of Figure 14C is effective, (e.g., as a cooling material), at pressures below atmospheric pressure, and is different than the contact cooling embodiment and the cryogen cooling embodiment described in Figure 14A. As described with reference to Figure 14A, the contact cooling embodiment and the cryogen cooling embodiment work effectively primarily at atmospheric pressure. As such, contact cooling and cryogen spray may not be effective at pressures below atmospheric pressure (e.g., one atmosphere). Materials that provide little evaporative cooling at atmospheric pressure may provide significant evaporative cooling at pressures less than one atmosphere. Water, for example, provides little evaporative cooling at atmospheric pressure, but “boils” at 60C in one third of an atmosphere and can provide significant evaporative cooling at one third of an atmosphere. These materials may be the material 1408 that is applied to the biological external tissue in the operation shown in Figure 14C.

[0096] There are other materials, substances, and liquids that could be used effectively for the material 1408. An important criterion is that the material 1408, at a desired temperature, have a vapor pressure equal to or higher than the pressure inside the device 1400 during treatment, (e.g., application of energy 1414 as described in Figure 14E). Many alcohols meet this criterion. Ethyl alcohol has a vapor pressure of -15PSI at 57C. Its heat of vaporization is 854 Joules per gram which is less than water’s 2450 Joules per gram. Nevertheless, ethyl alcohol may also provide elevated cooling at 55C as it carries off excess heat by vaporizing. In one embodiment, the material 1408 is applied prior to treatment. In another embodiment, the material 1408 is applied as a spray, wiped out using a sponge and/or other object and/or in any other suitable manner.

[0097] Next, in Figure 14D a negative pressure 1410 is applied to the device 1400. In one embodiment, as shown in Figure 11, the negative pressure is applied through the pressure conduit 1103. The negative pressure 1410 may

bring a portion of the biological external tissue 302 having the target 1404 upward within the inner chamber 1402 as illustrated in Figure 14D. In another embodiment, the negative pressure 1410 is applied after following the process described in Figures 2a, 2b, and 2c. Illustrated in Figure 14D, the negative pressure 1410 may reduce the pressure within the inner chamber 1402 below 1 ATM.

[0098] Then, in Figure 14E, the reduction of pressure within the inner chamber 1402 as described in Figure 14D may cause the material 1408 to change physical state (e.g., from a liquid to a gas). When the material 1408 changes from a liquid to a gas, it may undergo a process called vaporization 1412 as shown in Figure 14E.

[0099] The quantity of heat required to change the physical state of the material 1408 from a liquid to a gas through vaporization 1412 is called a heat of vaporization. For example, if the material 1408 is water, the heat of vaporization of water is 2450 Joules per gram. Prior to vaporization, the quantity of heat required to raise one gram of water one degree centigrade is called its specific heat. The specific heat of water is 4.184 Joules/gm. As liquid water is heated, every 4.184 Joules of energy that is applied to every gram of water heats that gram one degree centigrade. Assuming no heat losses, if 126 Joules of energy are applied to one gram of water, it will heat it from 30 degrees Centigrade to 60 degrees Centigrade. Adding another 168 Joules to this one gram of water will heat it to its "boiling point" at 100 degrees Centigrade.

[00100] The "boiling point" of water at atmospheric pressure is 100 degrees Centigrade. At the boiling point, it will require 2450 Joules before its temperature starts to rise above 100 degrees Centigrade. This is 35 times more energy than was needed to heat this one gram of water from 30C to 100C. At this time, this one gram of water will no longer be a liquid. It will be a gas.

[00101] At atmospheric pressure, the boiling point of water is 100 degrees Centigrade. At pressures less than atmospheric pressure (e.g., less than one

atmosphere), the “boiling point” of water is reduced. At a pressure of -12psi, the “boiling point” of water is 60C. As in the previous example, 126 Joules of energy is required to heat one gram of water from 30 Centigrade to 60 Centigrade. The temperature would then stop rising until 2450 Joules is applied to this one gram of water. If this water is on the biological external tissue 302 (e.g., skin), it may provide strong protection for the biological external tissue 302 rising above 60 Centigrade. Since it may require several seconds for biological external tissue (e.g., human skin) to burn at 60C, placing water on the skin in a reduced atmosphere may prevent burning.

[00102] Referring back to Figure 14E, an energy 1414 may also be applied to the biological external tissue 302 using the device 1400. In one embodiment, the energy 1414 is the same energy as described previously in Figures 2a, 2b, and 2c in operation 204. Specifically, the energy 1414 may be incoherent light, coherent light, radio frequency, and/or ultrasound, according to various embodiments of the invention. The energy 1414 may be a combination of multiple energies such as a radio frequency and a coherent light in some embodiments of the invention. Applying the energy 1414 may destroy and/or alter a targeted chromophore (e.g., a target 1404) or other target in the dermis and/or epidermis without injuring and/or burning the surrounding epidermis and dermis (e.g., as shown in Figure 1a) in the biological external tissue 302.

[00103] Lastly, in Figure 14F, the device 1400 may be removed from the biological external tissue 302 by applying a positive pressure 1416 to the biological external tissue 302 using the device 1400. The portion of the biological external tissue 302 having the target 1404 (as described in Figure 14D) may be pushed outside the inner chamber 1402 by the positive pressure 1416 as illustrated in Figure 14F. In one embodiment, the positive pressure is applied through the pressure conduits 1004 and 1003 as described in Figure 10. In another embodiment, the pressure within the inner chamber 1402 of the biological external tissue returns to 1 ATM in Figure 14F, from a pressure below

1 ATM in Figures 14D and 14E because the device 1400 is lifted from the biological external tissue 302. The seal 1406 between the device 1400 and the biological external tissue 302 as described in Figure 14B may be eliminated in the operation shown in Figure 14F. It should be noted that the target 1404 may be completely eliminated, (e.g., by the application of the energy 1414), by the time the operation as shown in Figure 14F is performed in one embodiment.

[00104] Figure 15 is a cross-sectional view of a device 1500 having a body that is applied to biological external tissue 302, the device 1500 having multiple vacuum chambers (conduits 1004, 1103, 1003 as previously described in Figure 11) and a material conduit 1502 thru which the material 1408 is applied to the biological external tissue 302, according to one embodiment. The device 1500 in Figure 15 is similar to the device 1100 shown in Figure 11, except the device 1500 includes the material conduit 1502. In one embodiment, the material 1408 is applied through the conduit 1502 as shown on the device 1500 in Figure 15. In another embodiment, the material 1408 is water and/or ethyl alcohol.

[00105] Figure 16 is an operation flow of a method of reducing pressure of an inner chamber and applying a material to the biological external tissue, according to one embodiment. In operation 1602, a device (e.g., the device 2400 as illustrated in Figure 24, the device 1400 as illustrated in Figure 14, and/or the devices illustrated in Figures 3-12, etc.) having an outer portion 2402 (e.g., as illustrated in Figure 24) and an inner chamber 2404 (as illustrated in Figure 24) is applied to the biological external tissue 302 (as illustrated in Figure 24) such that the outer portion 2402 contacts the biological external tissue 302 and the inner chamber 2404 occupies a space above the biological external tissue 302.

[00106] In operation 1604 of Figure 16, a vacuum seal (e.g., a seal 1406 as described in Figure 14B) is formed between the outer portion 2402 and the biological external tissue 302. In operation 1606, the pressure of the inner chamber 2404 is reduced to a first pressure that is below atmospheric pressure (e.g., as shown in Figure 14D) to bring at least some of the biological external

tissue 302 into the inner chamber 2404 (e.g., and/or alternatively inner chamber 1402 as illustrated in Figures 14A-F).

[00107] In operation 1608, a liquid (e.g., water and/or other material 1408 as illustrated in Figure 14C) is furnished to the biological external tissue 312 inside the inner chamber 2404 (as shown in Figure 24). In operation 1610, an energy (e.g., the energy 1414 as shown in Figure 14E) is applied to the biological external tissue 302 inside the inner chamber 2404. In operation 1612, the liquid (e.g., material 1408) evaporates (e.g., through vaporization 1412 as shown in Figure 14E and/or through other means). In operation 1614, the vacuum seal (e.g., seal 1406 in Figure 14B) is released to allow the device (e.g., the device 2400 of Figure 24) to be released before the biological external tissue 302 is damaged (e.g., burned). It will be appreciated that other embodiments of the implementation shown in Figure 16 may have a different sequence of operations. For example, operation 1608 may precede operation 1606.

[00108] Figure 17 is another example of an embodiment of the invention. In operation 1702, a device (e.g., such as cut-away view 2300 in Figure 23 of the device 1400 in Figure 14A) having a cavity 2308 is applied to a biological external tissue 302 (e.g., as illustrated in Figures 3-24), such that a chamber (e.g., the inner chamber 1402 as illustrated in Figure 14A) over the biological external tissue 302 is formed. In operation 1704, a vacuum seal (e.g., a seal 1406 as illustrated in Figure 14B) of an outer cut-away 2310 (e.g., the outer cut-away 2310 in Figure 23 may be a cross-sectional view of the outer portion 2402 in Figure 24) and the biological external tissue 302 is formed. In operation 1706, the pressure of the chamber (e.g., the inner chamber 1402 as illustrated in Figure 14A) is reduced to a pressure that is below atmospheric pressure to bring at least a portion of the biological external tissue 302 into the chamber. In operation 1708, a liquid (e.g., water and/or other material 1408) is applied to the portion of the biological external tissue 302 inside the chamber (e.g., the inner chamber 1402 as illustrated in Figure 14A). In operation 1710, the liquid evaporates (e.g.,

through vaporization 1412 as shown in Figure 14E and/or through other means). In operation 1712, an energy (e.g., the energy 1414 as shown in Figure 14E) is applied to the portion of the biological external tissue 302 inside the chamber to eradicate a target (e.g., the target 1404 in Figure 14A) within the biological external tissue 302. It will be appreciated that other implementations of the method of Figure 17 may use a different sequence of operations.

[00109] Figure 18 is an operation flow of a method of coating a liquid on an area of biological external tissue, forming a pressure equal to or lower than a vapor pressure of the liquid, and applying an energy to a target before the blood concentration in the biological external tissue returns to at least a normal state, according to one embodiment. In operation 1802, a device (e.g., a cut-away view 2300 as illustrated in Figure 23 and/or a device 2400 as illustrated in Figure 24) is applied to an area of biological external tissue 302 having a target 1404. In operation 1804, a liquid (e.g., water and/or other material 1408) is coated on the area of biological external tissue 302 to be treated. In operation 1806, a first positive pressure (e.g., as described in Figure 2c in operation 202c) is applied on the area. In operation 1808, a negative pressure (e.g., as described in Figure 2c in operation 203, and as illustrated in Figure 14D) is applied on the area to bring the biological external tissue 302 into contact with the device that is above the area. In operation 1810, a pressure is formed equal to a vapor pressure of the liquid (e.g., to vaporize the liquid as illustrated in vaporization 1412 of Figure 14E). In operation 1812, an energy is applied to the target 1404 before the blood concentration in the area returns to at least a normal state. In operation 1814, a second positive pressure is applied on the area to allow the device to be released from the area before the biological external tissue 302 is damaged (e.g., as described in Figure 2c in operation 202d and as illustrated in Figure 14F). It will be appreciated that other implementations of the method of Figure 18 may use a different sequence of operations.

[00110] Figure 19 is an exemplary embodiment of a method which includes depositing a material on an area of a biological external tissue having a target, applying a device to the area, and bringing the biological external tissue into contact with a protruding object of the device that is above the area. In operation 1902, a material 1408 (as illustrated in Figure 14C) is deposited on an area of biological external tissue 302 having a target 1404. In operation 1904, a device (e.g., a device 500 as illustrated in Figure 5 and/or a device 1400 as illustrated in Figure 14A-F) is applied to the area. In operation 1906, a negative pressure is applied on the area to bring the biological external tissue into contact with a protruding object (e.g., object 401 in Figure 4 and Figure 5) of the device that is above the area (e.g., as described in Figure 5). In operation 1908, an energy (e.g., an energy 1414) is applied to the target 1404 before the blood concentration in the area of biological external tissue 302 returns to at least a normal state. It will be appreciated that other implementations of the method of Figure 11 may use a different sequence of operations.

[00111] Figure 20 is another exemplary embodiment of a method which includes reducing temperature of an area of a biological external tissue having a target by depositing a material on the area, applying a negative pressure to bring the biological external tissue closer to and/or into contact with the device, and applying an energy to the target before the blood concentration in the area returns to at least a normal state, according to one embodiment. In operation 2002, temperature of an area of biological external tissue 302 having a target 1404 is reduced by depositing a material 1408 on the area of biological external tissue 302. In operation 2004, a device (e.g., a device 1400 of Figure 14A-F) is applied to the area. In operation 2006, a negative pressure (e.g., negative pressure 1410 in Figure 14D) is applied on the area to bring the biological external tissue closer to and/or into contact with the device (e.g., as described and illustrated in Figure 14D). In operation 2008, an energy (e.g., an energy 1414) is applied to the target 1404 before the blood concentration in the area returns to at least a normal state.

In operation 2010, a positive pressure (e.g., positive pressure 1416 in Figure 14F) is applied on the area to allow the device to be released from the area before the biological external tissue 302 is damaged (e.g., as described and illustrated in Figure 14F). It will be appreciated that other implementations of the method of Figure 20 may use a different sequence of operations.

[00112] Figure 21 is a graph illustrating the vaporization pressure in PSI of ethyl alcohol and water as a function of temperature in Celsius, according to one embodiment. There are two curves illustrated in chart 2100 in Figure 21, one curve 2102 for ethyl alcohol, and another curve 2104 for water. The ethyl alcohol curve 2102 shows various vaporization pressures as a function of temperature. For example, at a temperature of 60 degrees Celsius, the vaporization pressure of ethyl alcohol is approximately -8 PSI. As another example, at a temperature of 60 degrees Celsius, the vaporization pressure for water is slightly below -12 PSI.

[00113] Figure 22 is a graph illustrating the time in seconds to burn biological external tissue, according to one embodiment. The single curve in Figure 22 illustrates an exponential decline in the number of seconds it takes to burn biological external tissue (e.g., human skin) as temperature increases. For example, at a temperature of 58 degrees Celsius, it takes slightly under 10 seconds to burn skin, whereas at a temperature of 64 degrees Celsius, it takes only 2 seconds to burn skin.

[00114] Figure 23 is a three-dimensional, cut-away view of a device to treat biological external tissue according to one embodiment. Portions of Figure 23 have been previously described in detail in conjunction with Figure 17. Figure 23 illustrates a cut-away view 2300 (e.g., the cut-away view 2300 may be a three-dimensional cross-sectional view of a device 2400 as illustrated in Figure 24) having a cavity 2308 and an outer cut-away 2310 for treating the biological external tissue 302 having a target 1404.

[00115] In addition, the cut-away view 2300 in Figure 23 also includes a port 2302, a port 2304, and port 2306. While three ports (2302, 2304, and 2304) are illustrated, other embodiments may have any number of ports or no ports at all. The ports 2302 and 2306 may be used to pressure conduits 1004 and 1003 as illustrated in Figure 11 to connect to the cut-away view 2300 in one embodiment (e.g., to allow a seal 1406 to be formed as illustrated in Figure 14D). The port 2304 may be used to allow the conduit 1103 (as illustrated in Figure 11) to connect to the cut-away view 2300 in another embodiment (e.g., to allow the negative pressure in Figure 14D and the positive pressure in Figure 14F to be applied). The ports 2302 and 2306 may form a chamber that is separate and isolated from the chamber above the target 1404 (e.g., the inner chamber 1402 as illustrated in Figure 14A may be separate and isolated from the chamber that forms the seal 1406 in Figure 14B). In one embodiment, an object (e.g., an object 401 of Figure 4) on the cut-away view 2300 contacts the biological external tissue 302 within the chamber above the target 1404 and pushes blood within the biological external tissue 302 surrounding the target 1404 outside the chamber. Also illustrated in Figure 23 is a number of energy panel 2312. Each energy panel 2312 may be connected to one or more energy sources (e.g., energy sources 503a-c as illustrated in Figure 5).

[00116] Figure 24 is a three-dimensional view of a device 2400 having an inner chamber 2404 and an outer portion 2402 to treat biological external tissue 312 according to one embodiment. Portions of Figure 24 have been previously described in detail in conjunction with Figure 16. In addition, the inner chamber 2404 in Figure 24 may completely cover the target 1404 as illustrated in Figure 24. Furthermore, the inner chamber 2404 may be completely isolated (e.g., isolated pressure wise) from the outer portion 2402. In addition, a camera and/or video recording device (not shown) having a lens may be connected to the device 2400 so that a user can view the biological external tissue within the inner chamber 2404. In another embodiment, the inner portion may be manually

aligned (e.g., through physical marking of the biological external tissue 302 around the target 1404, and/or by replacing a removable and adjustable size fitting (not shown) for the inner chamber 2404 prior to application of the device 2400 onto the biological external tissue, etc.).

[00117] Various sensor(s) 2406 may be installed on the device 2400 in one embodiment. Various sensor(s) 2406 may include skin color sensors, temperature sensors, motion sensors, vapor pressure sensors (e.g., to sense negative and/or positive pressure within a chamber), material sensors (e.g., to sense the presence of water or other material within the chamber), temperature sensors, capacitance sensors, and a variety of other types of sensors and/or electronics described in Figures 1-13. Furthermore, the device 2400 may include a vacuum 2408 that generates a negative pressure within the outer portion 2402 to seal (e.g., the seal 1406 as illustrated in Figure 14) the device 2400 to the biological external tissue 302.

[00118] The device 2400 in Figure 24 may include one or more energy source(s) 2412. The energy source(s) 2412 may deliver energy 1414 as described in Figure 14E. In another embodiment, energy source(s) 2412 may be energy sources described in Figures 3-13 (e.g., energy source 503a-c as illustrated in Figure 5). The device 2400 may also include a liquid/negative pressure applicator 2410 to apply liquid/negative pressure to the inner chamber 2404. In one embodiment, the liquid/negative pressure applicator 2410 applies the material 1408 to the biological external tissue 302 within the inner chamber 2404. In another embodiment, the liquid/negative pressure applicator 2410 applies a negative pressure to the biological external tissue 302 within the inner chamber 2404 to bring the target 1404 and surrounding biological external tissue 302 into the inner chamber 2404.

[00119] It should be noted that the various embodiments having sensors, and electronics described herein may be performed within hardware circuitry as well as in software. Specifically, it should be noted that an electrical architecture for

a handheld device as described in Figure 13 can be implemented with one or more semiconductor devices including circuitry such as logic circuitry to perform its various functions as described above, in addition to being implemented in software. In some embodiments, hardware circuitry may provide speed and performance advantages over software implementations of the device 1301 shown in Figure 13. In other embodiments, software implementations may be preferred. In one embodiment, the sensors 1305 in Figure 13 may be designed using an electrical skin contact sensor circuit, a pressure sensor circuit, a skin temperature circuit, and/or any combination of these sensor circuits, and may be built with semiconductor circuitry (e.g., logic circuitry such as CMOS based circuitry). A semiconductor chip may implement the functions (e.g., as described in Figures 2 thru Figure 24) described within the various embodiments using logic gates, transistors, and hardware logic circuitry associated with implementing the various embodiments disclosed herein.

[00120] The subject invention has been described with reference to numerous details set forth herein and the accompanying drawings. This description and accompanying drawings are illustrative of the invention and are not to be construed as limiting the invention. It will be evident that various modifications may be made thereto without departing from the broader spirit and scope of the invention as set forth in the following claims.

IN THE CLAIMS

What is claimed:

1. A method to treat a target, comprising:
 - furnishing a liquid to a biological external tissue inside an inner chamber;
 - applying an energy to the biological external tissue inside the inner chamber; and
 - causing the liquid to evaporate.
2. The method claim 1, further comprising applying a device having an outer portion and the inner chamber to the biological external tissue such that the outer portion contacts the biological external tissue and the inner chamber occupies a space above a portion of the biological external tissue having the target.
3. The method of claim 2, further comprising:
 - displaying at least one measurement of a sensor on the device;
 - providing power to the device; and
 - generating a positive pressure and a negative pressure inside the inner chamber through a pressure source connected to the device through a cable element.
4. The method of claim 2, further comprising reducing pressure of the inner chamber to a first pressure that is below atmospheric pressure to bring at least some of the biological external tissue into the inner chamber.
5. The method of claim 2, further comprising preventing the biological external tissue that is outside the device from stretching.
6. The method of claim 5, further comprising forming a vacuum seal between the outer portion and the biological external tissue.

7. The method of claim 5, further comprising releasing the vacuum seal to allow the device to be removed before the biological external tissue is damaged.
8. The method of claim 1, wherein the causing the liquid to evaporate is performed through vaporization during application of the energy to treat the target.
9. The method of claim 8, wherein the energy originates from a source that is not exposed to any pressure inside the inner chamber.
10. The method of claim 8, wherein the energy is at least one of an incoherent light, a coherent light, a radio frequency, or an ultrasound.
11. The method of claim 8, further comprising automatically regulating a power level of the energy.
12. The method of claim 1, further comprising applying an electrical current to the target before a blood concentration in the biological external tissue returns to at least a normal state or higher concentration than normal.
13. The method of claim 1, further comprising measuring a color of the biological external tissue.
14. The method of claim 1, further comprising measuring a temperature of the biological external tissue.
15. The method of claim 1, further comprising: pushing away blood inside the biological external tissue.

16. A device that applies energy to a biological external tissue, the device comprising:

- an outer portion to form a vacuum seal of the outer portion and the biological external tissue;
- a chamber encompassed by the outer portion having a pressure below atmospheric pressure to bring at least a portion of the biological external tissue into the chamber; and
- a material in the chamber to vaporize at the pressure below atmospheric pressure without damaging the biological external tissue.

17. The device of claim 16, further comprising an object on the device above the chamber, to contact the biological external tissue and to push blood within the portion of the biological external tissue outside the chamber.

18. The device of claim 16, further comprising:

- at least one energy panel on the device, the at least one energy panel being used to deliver energy to the biological external tissue; and
- at least one port on the device to deliver positive and negative pressure to the chamber.

19. The device of claim 16, further comprising:

- a pair of electrodes connected to opposite sides of the device to apply an electrical current through the biological external tissue; and
- a pressure conduit coupled to the device to generate a pressure in an area that includes the biological external tissue, and a protruding object of the device that is above the biological external tissue to contact the biological external tissue.

20. The device of claim 19, wherein at least a portion of the biological external tissue is brought into the chamber through the pressure generated by the pressure conduit.

21. The device of claim 16, further comprising:

a display element on the device to display at least one parameter with respect to a treatment of the biological external tissue, the display element having rows and columns of pixels controlled by a display controller; and

an energy source coupled to the device to deliver an energy to the biological external tissue.

22. The device of claim 21, wherein the energy source is not exposed to any pressure inside the chamber.

23. The device of claim 21, wherein the energy is at least one of an incoherent light, a coherent light, a radio frequency, or an ultrasound.

24. The device of claim 23, further comprising automatically regulating a power level of the energy.

25. The device of claim 16, further comprising at least one sensor connected to the device chosen from a group comprising a skin color sensor, a temperature sensor, a motion sensor, a vapor pressure sensor, a material sensor, and a capacitance sensor.

26. The device of claim 16, wherein the material is at least one of water and ethyl alcohol.

27. A method of treating an area of biological external tissue having a target using a device, comprising:
- coating a liquid on the area;
 - applying a first positive pressure on the area;
 - applying a negative pressure on the area to bring the biological external tissue closer to the device that is above the area;
 - forming a pressure equal to or lower than a vapor pressure of the liquid;
 - applying an energy to the target before the blood concentration in the area returns to at least a normal state; and
 - applying a second positive pressure on the area to allow the device to be released from the area before the biological external tissue is damaged.
28. The method of claim 27, further comprising displaying at least one measurement of a sensor on the device.
29. The method of claim 28, wherein the device is a handheld device.
30. The method of claim 28, wherein the at least one sensor is chosen from a group comprising a skin color sensor, a temperature sensor, a motion sensor, a vapor pressure sensor, a material sensor, and a capacitance sensor.
31. The method of claim 27, further comprising causing the liquid to evaporate.
32. The method of claim 27, wherein the energy originates from a source that is not exposed to any pressure applied by the device.
33. The method of claim 27, further comprising: pushing away blood inside the biological external tissue.

34. The method of claim 27, wherein the liquid is one of water and ethyl alcohol.

35. A method for treating a target with a device, the method comprising:
depositing a material on an area of a biological external tissue having the target;
applying the device to the area;
applying a negative pressure on the area to bring the biological external tissue into contact with a protruding object of the device that is above the area; and
applying an energy to the area before the blood concentration in the area returns to at least a normal state, and causing the material to evaporate.

36. The method of claim 35, further comprising applying a positive pressure on the area and then removing the device from the area.

37. The method of claim 35, wherein the material is applied during application of the energy and wherein the material provides evaporative cooling.

38. A system to treat biological external tissue using a device, comprising:
means for reducing temperature of an area of biological external tissue having a target by depositing a material on the area;
means for applying a negative pressure on the area to bring the biological external tissue into contact with the device; and
means for applying an energy to the target before the blood concentration in the area returns to at least a normal state.

39. The system of claim 38, further comprising means for applying a positive pressure on the area to allow the device to be released from the area before the biological external tissue is damaged.

40. The system of claim 38, wherein the material has a vapor pressure below atmospheric pressure.

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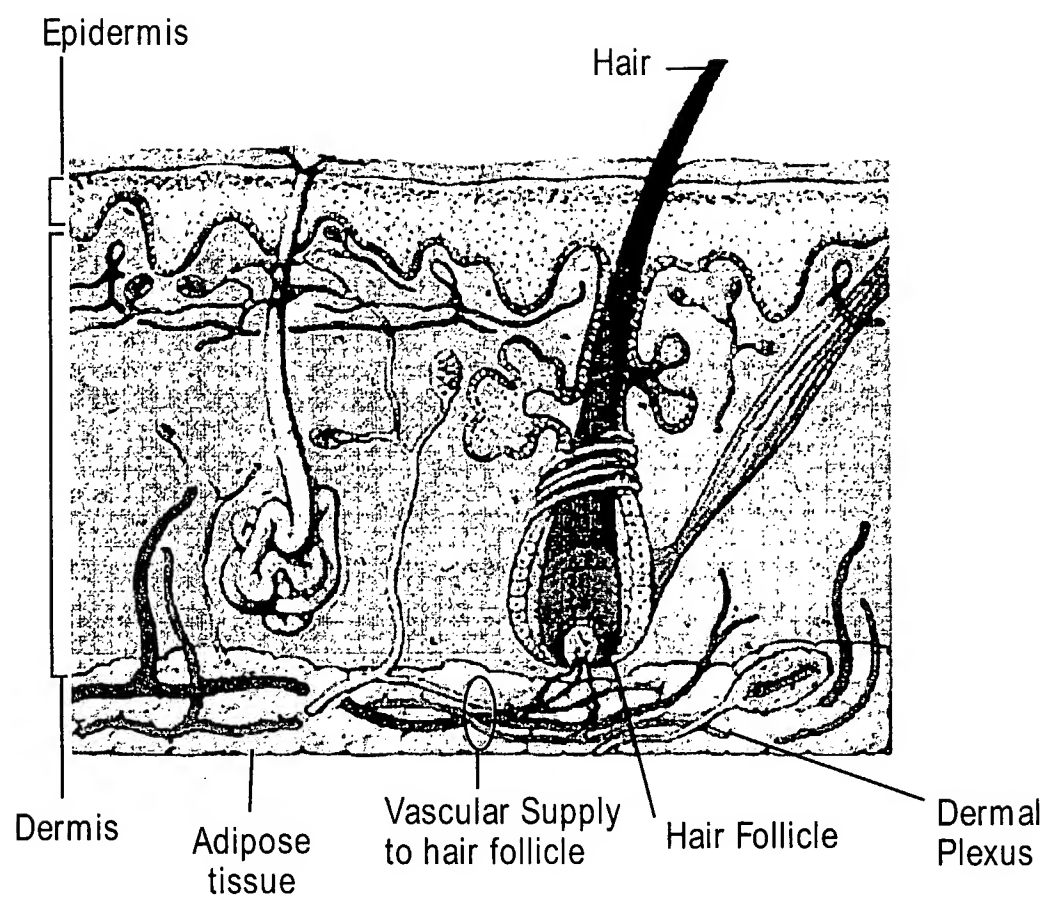


FIG. 1a

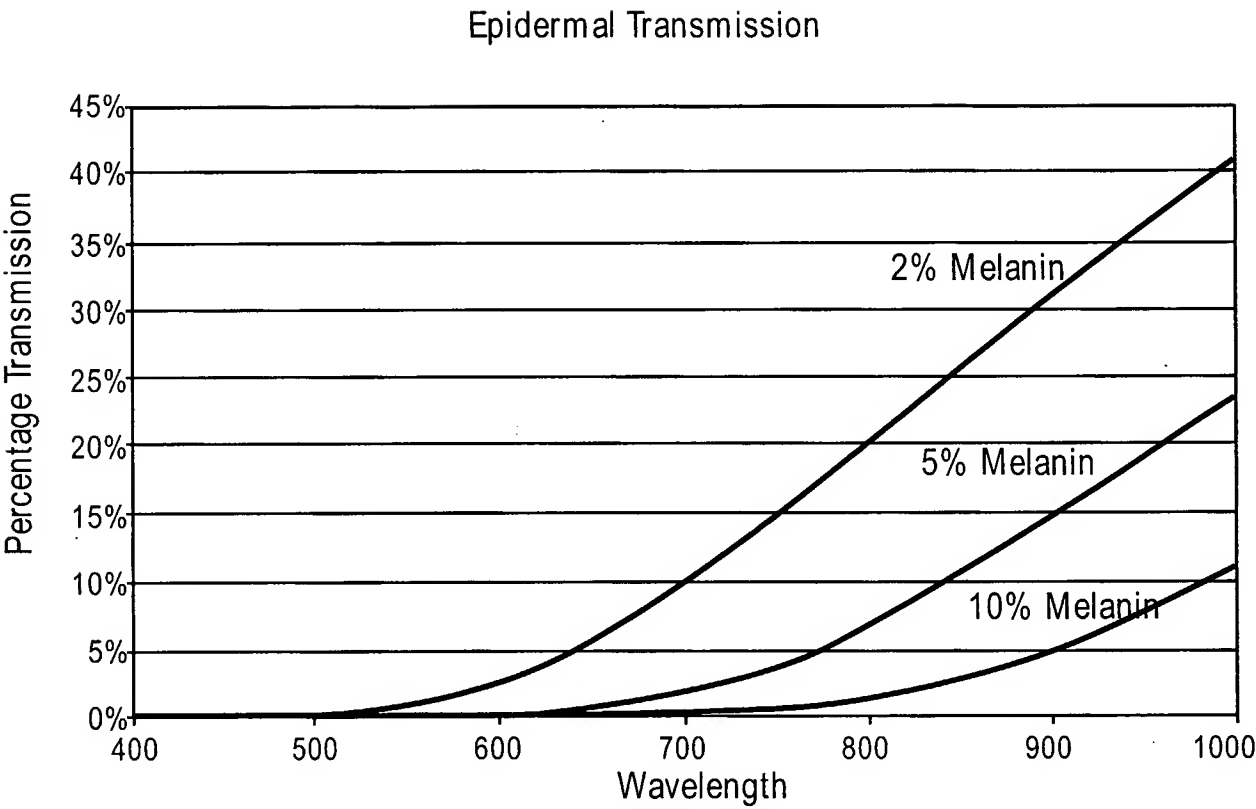


FIG. 1b

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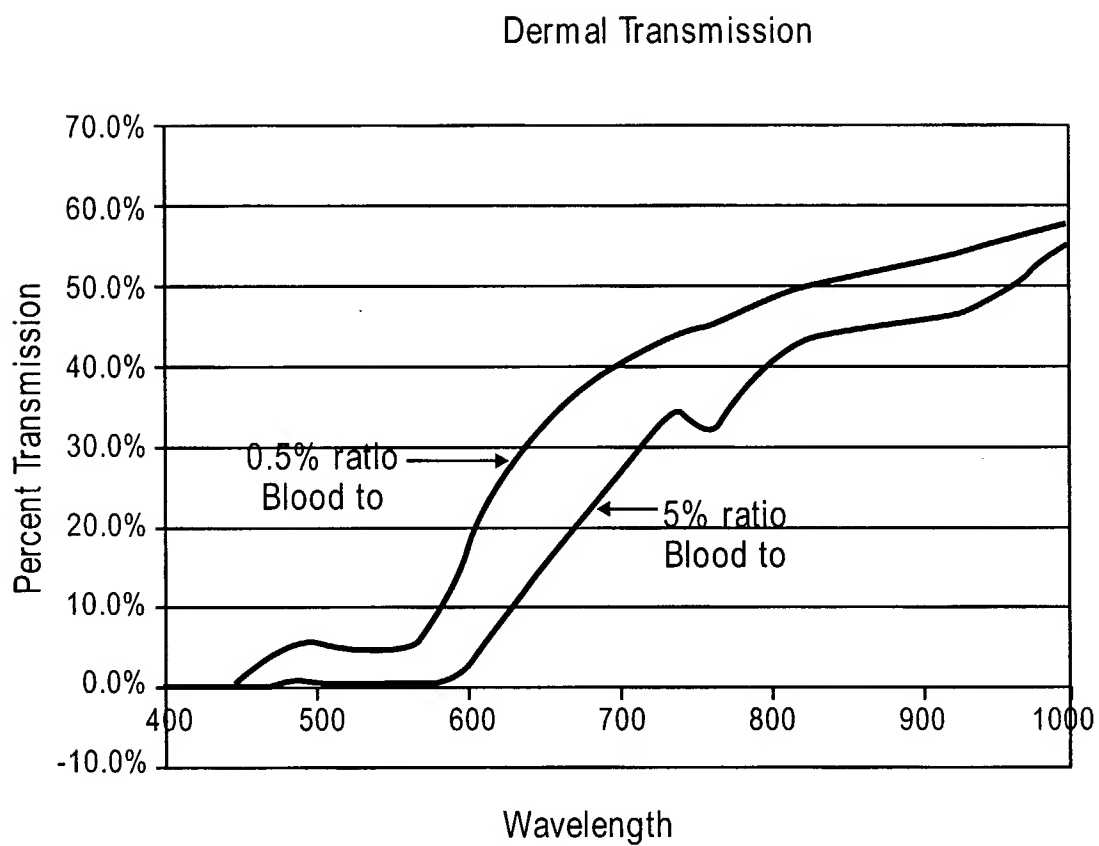


FIG. 1c

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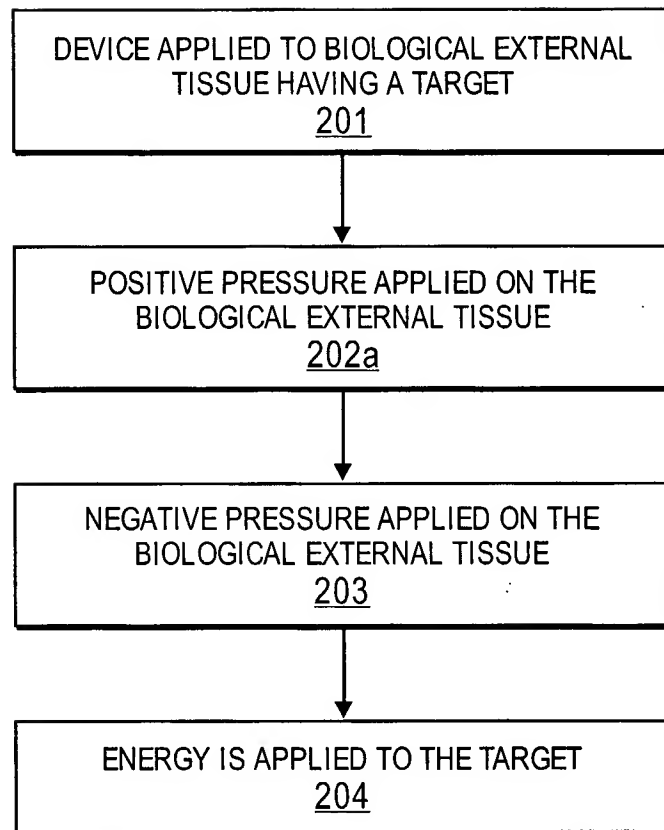


FIG. 2a

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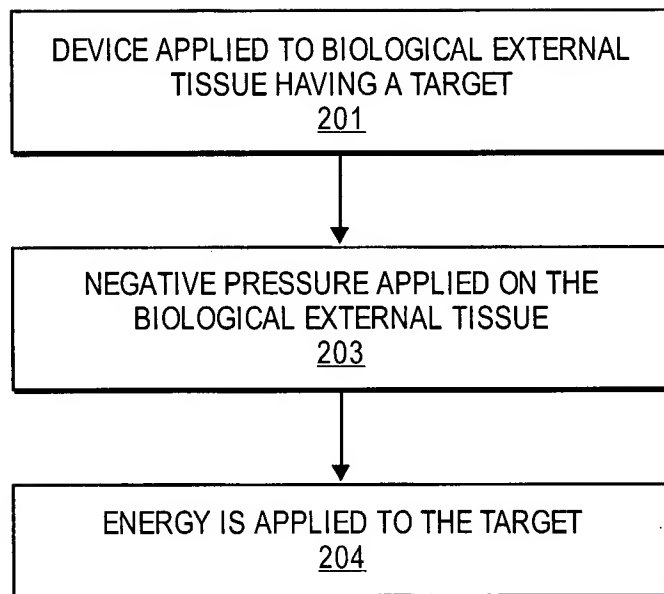


FIG. 2b

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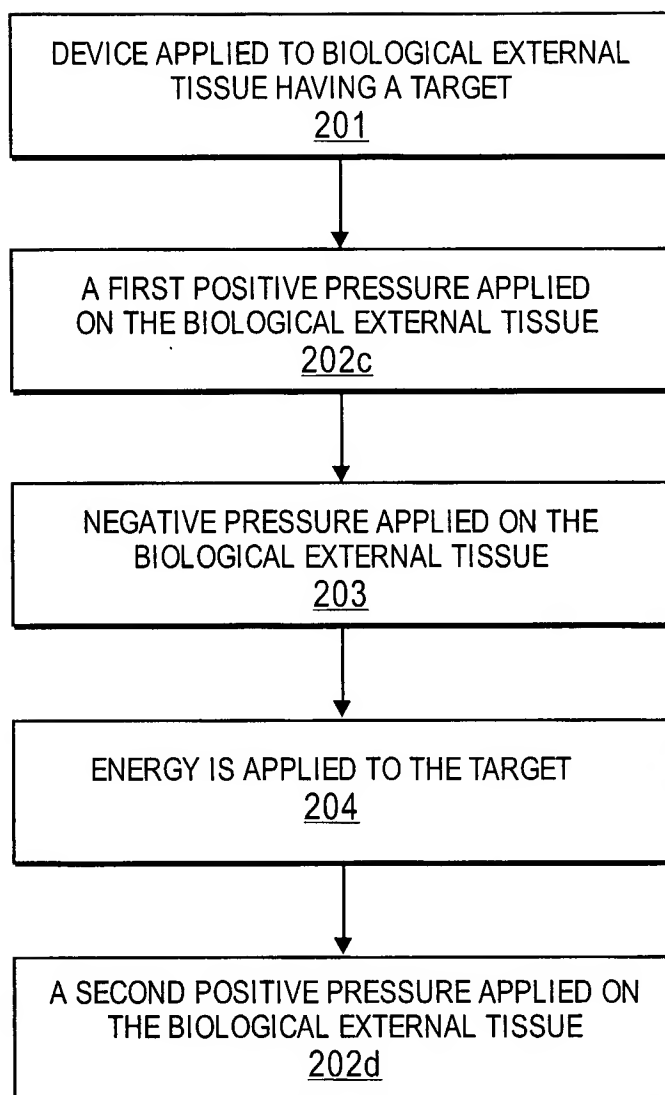


FIG. 2c

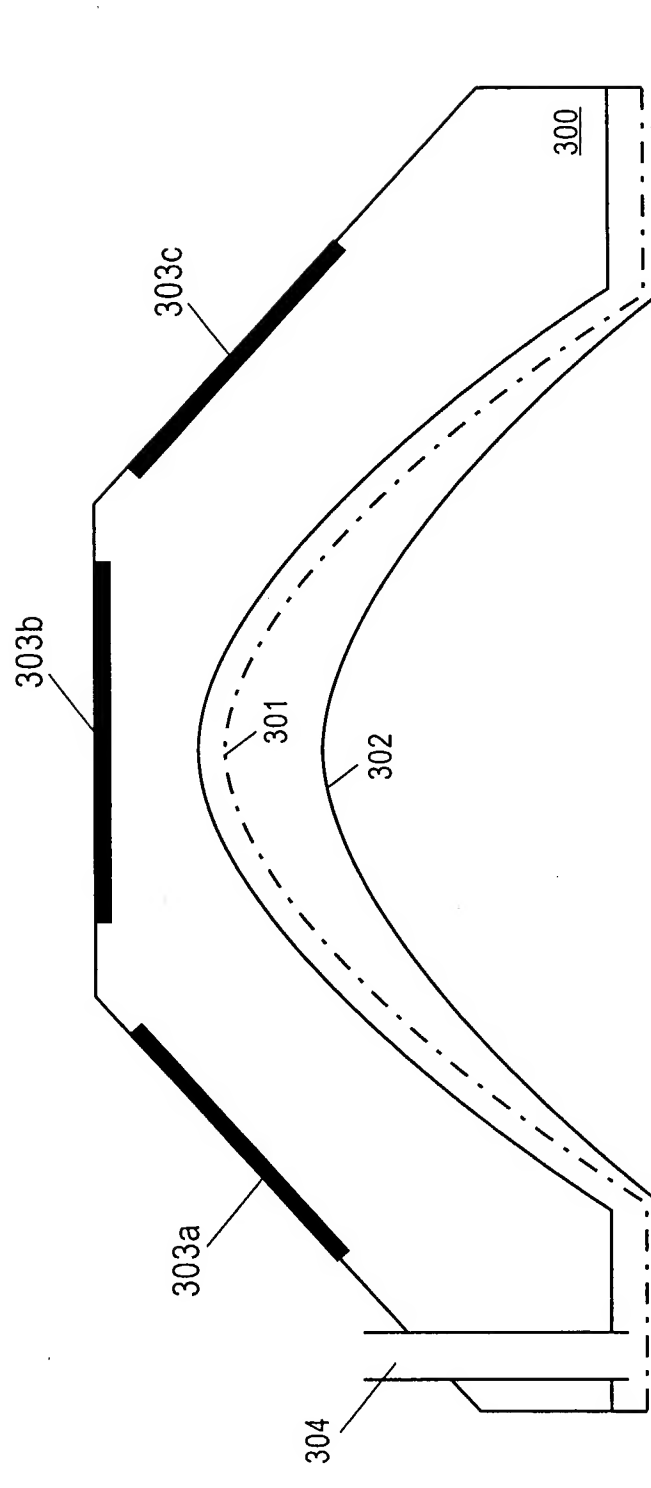


FIG. 3

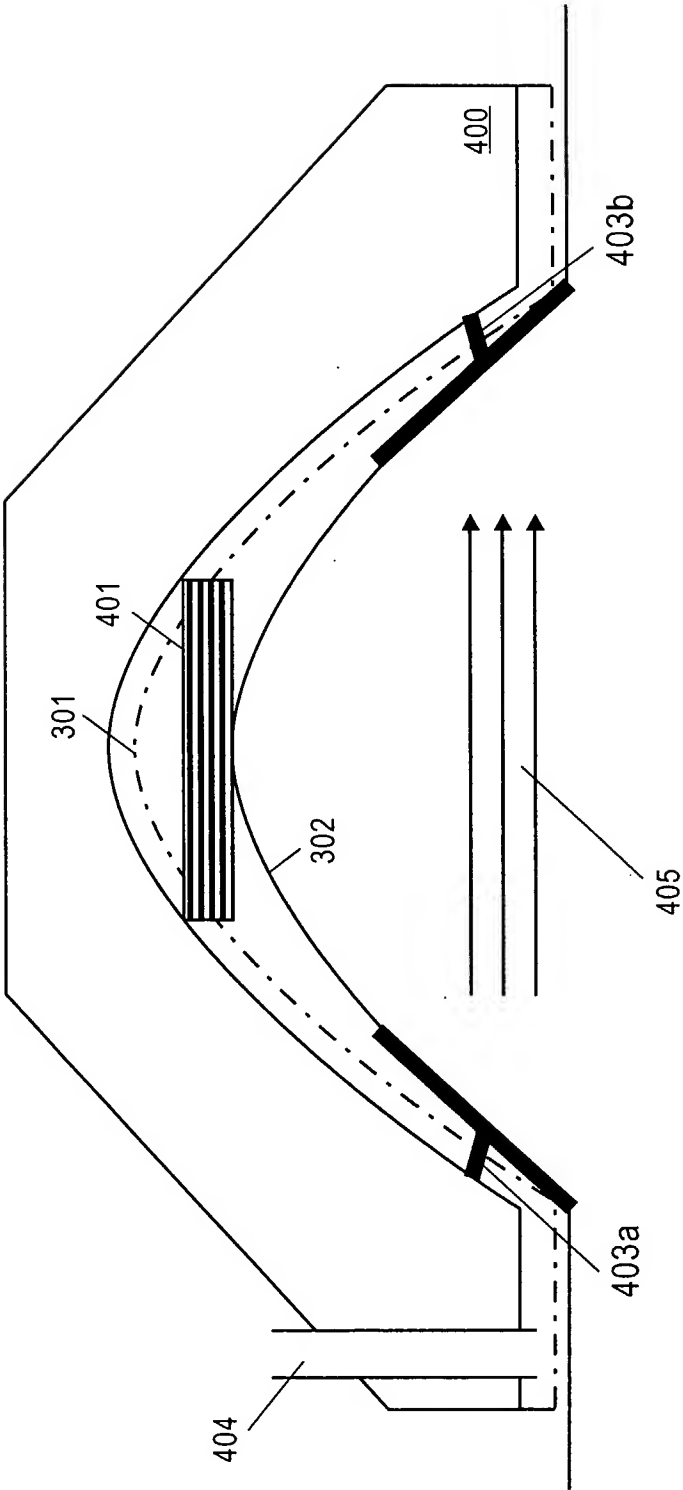
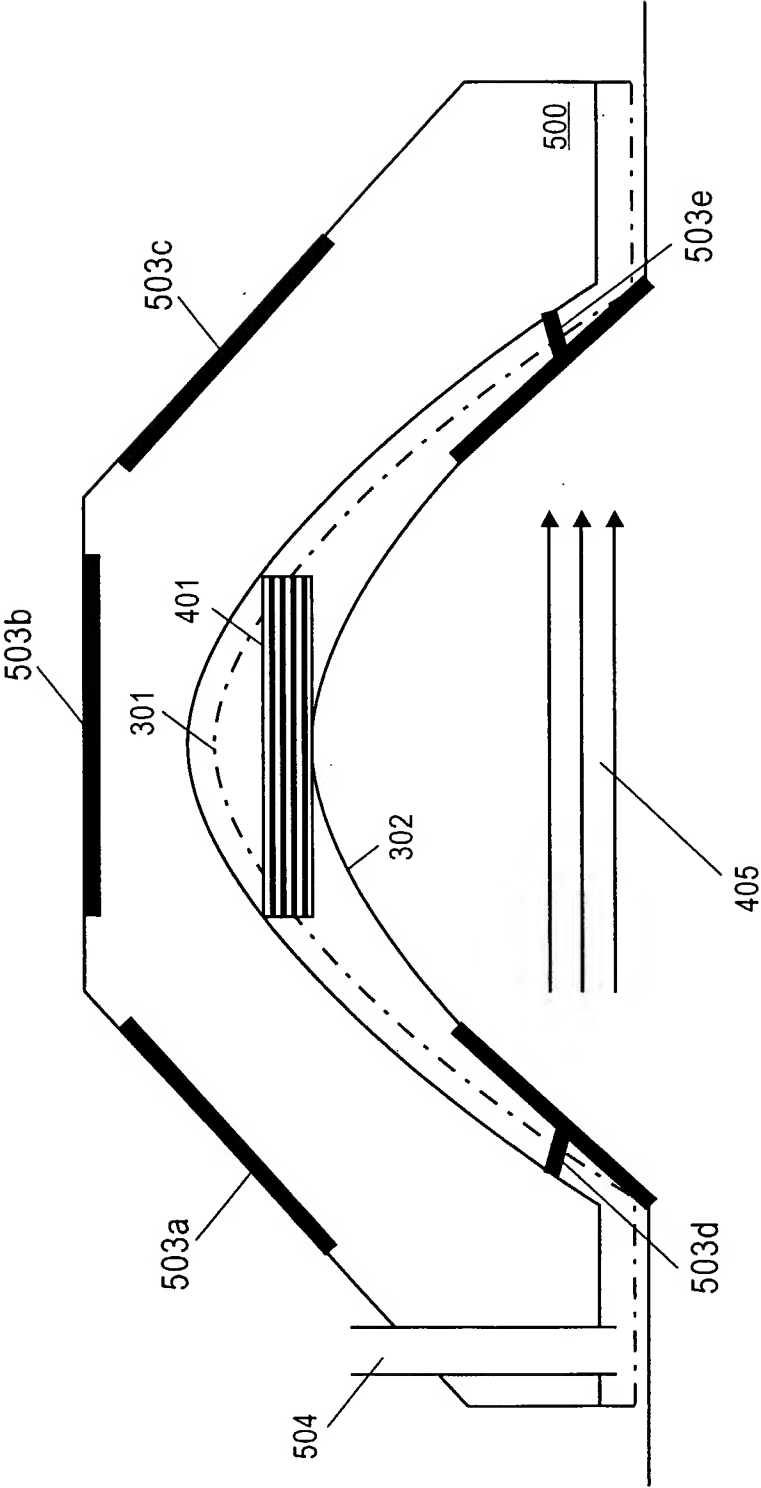


FIG. 4

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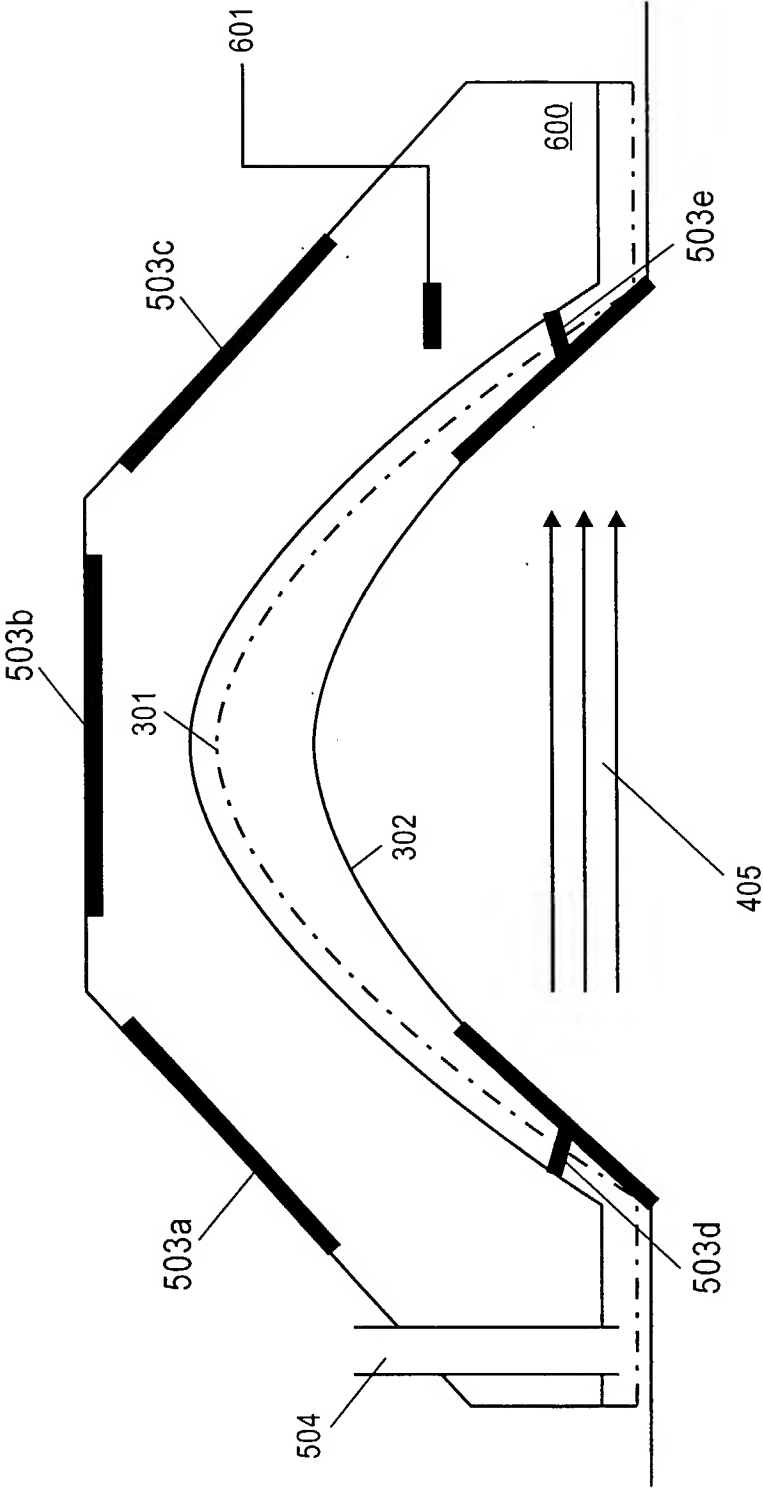


FIG. 6

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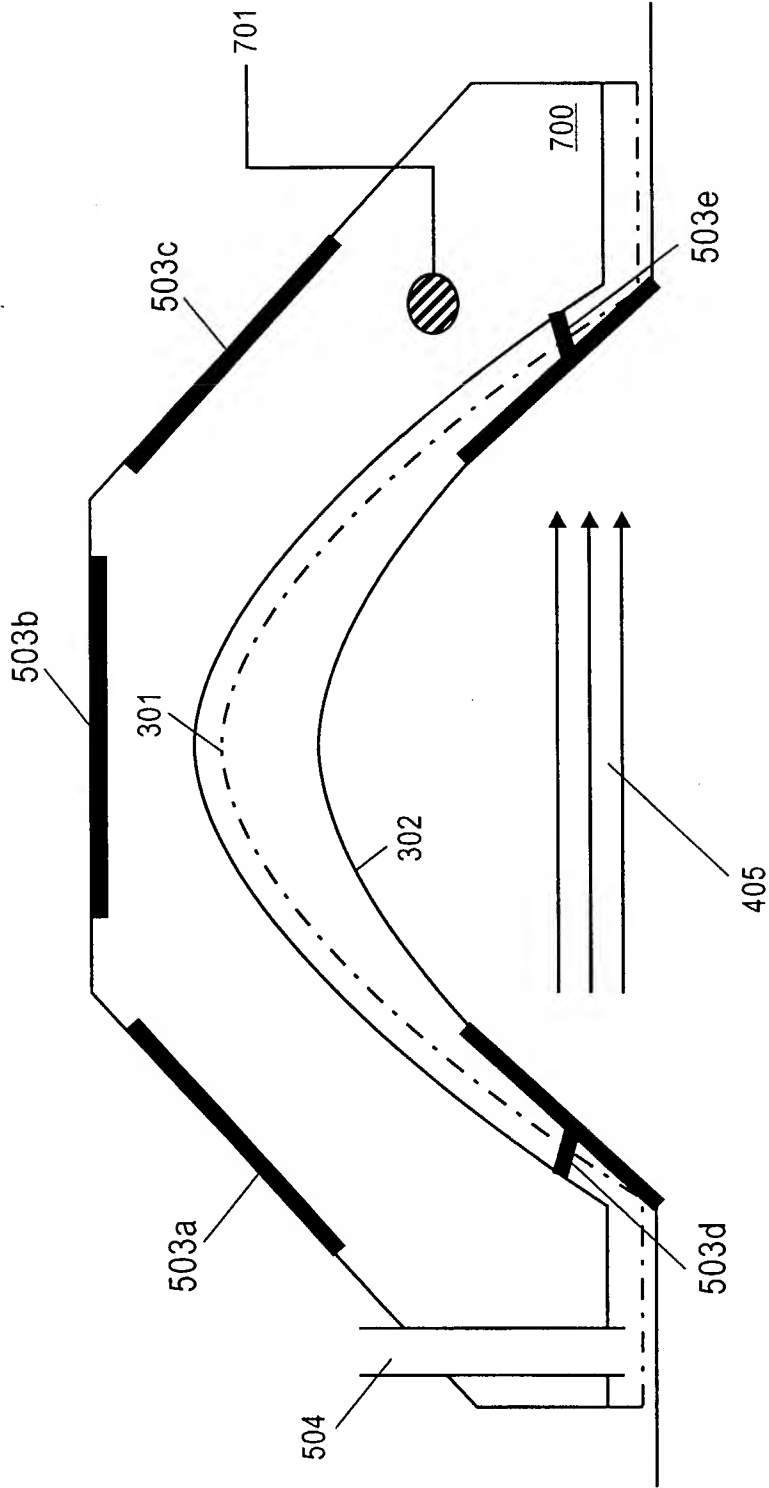


FIG. 7

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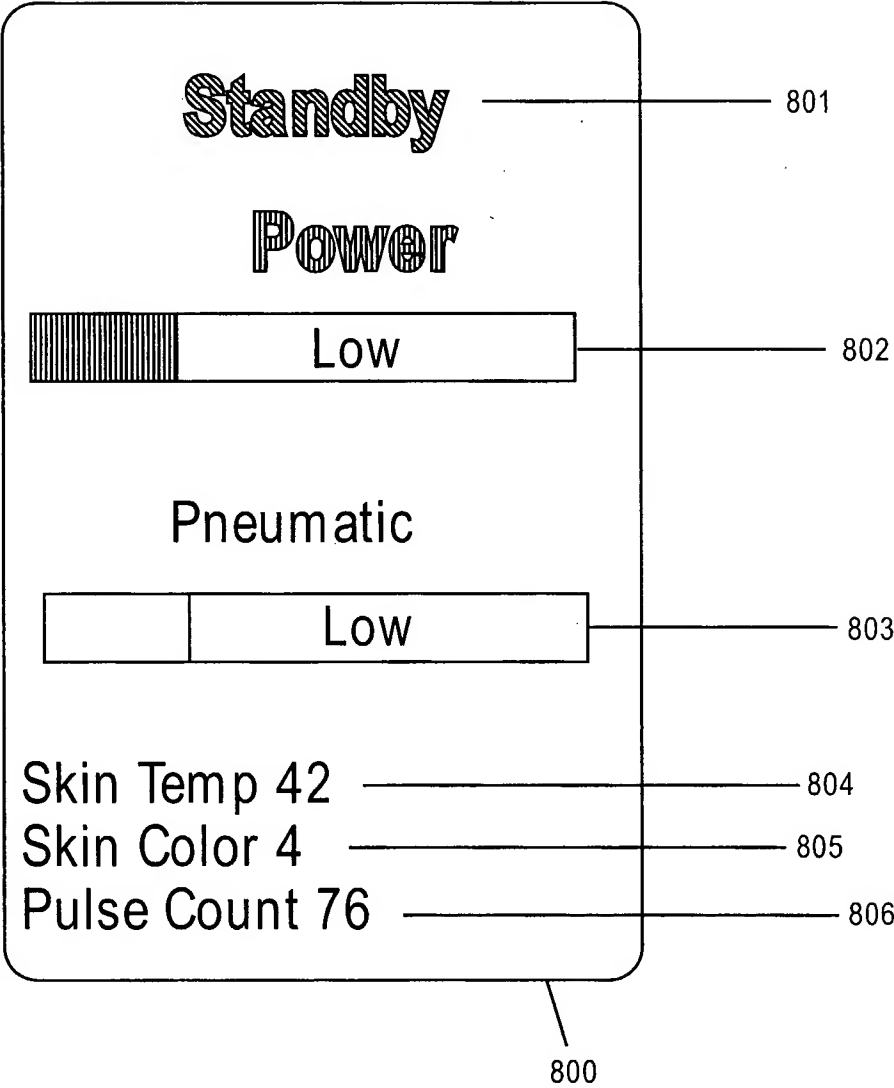


FIG. 8

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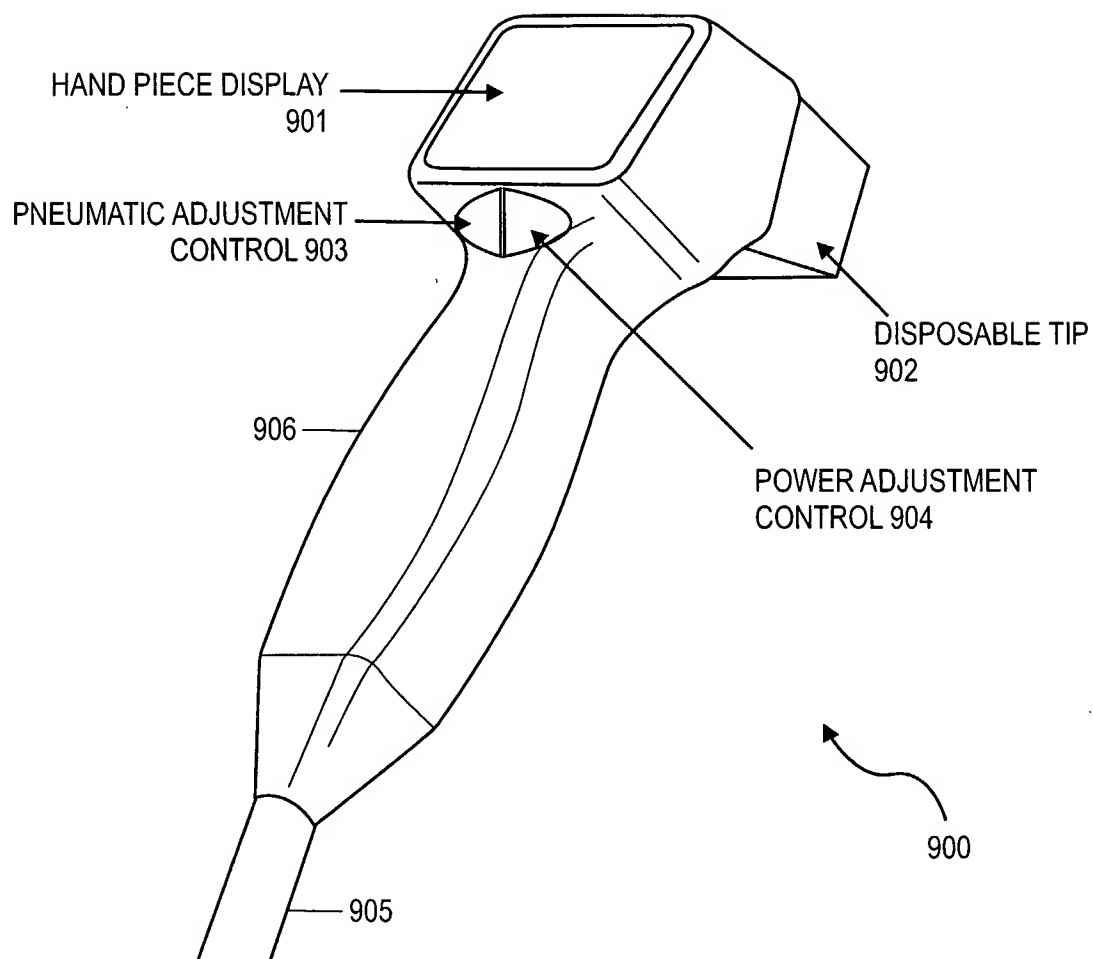


FIG. 9

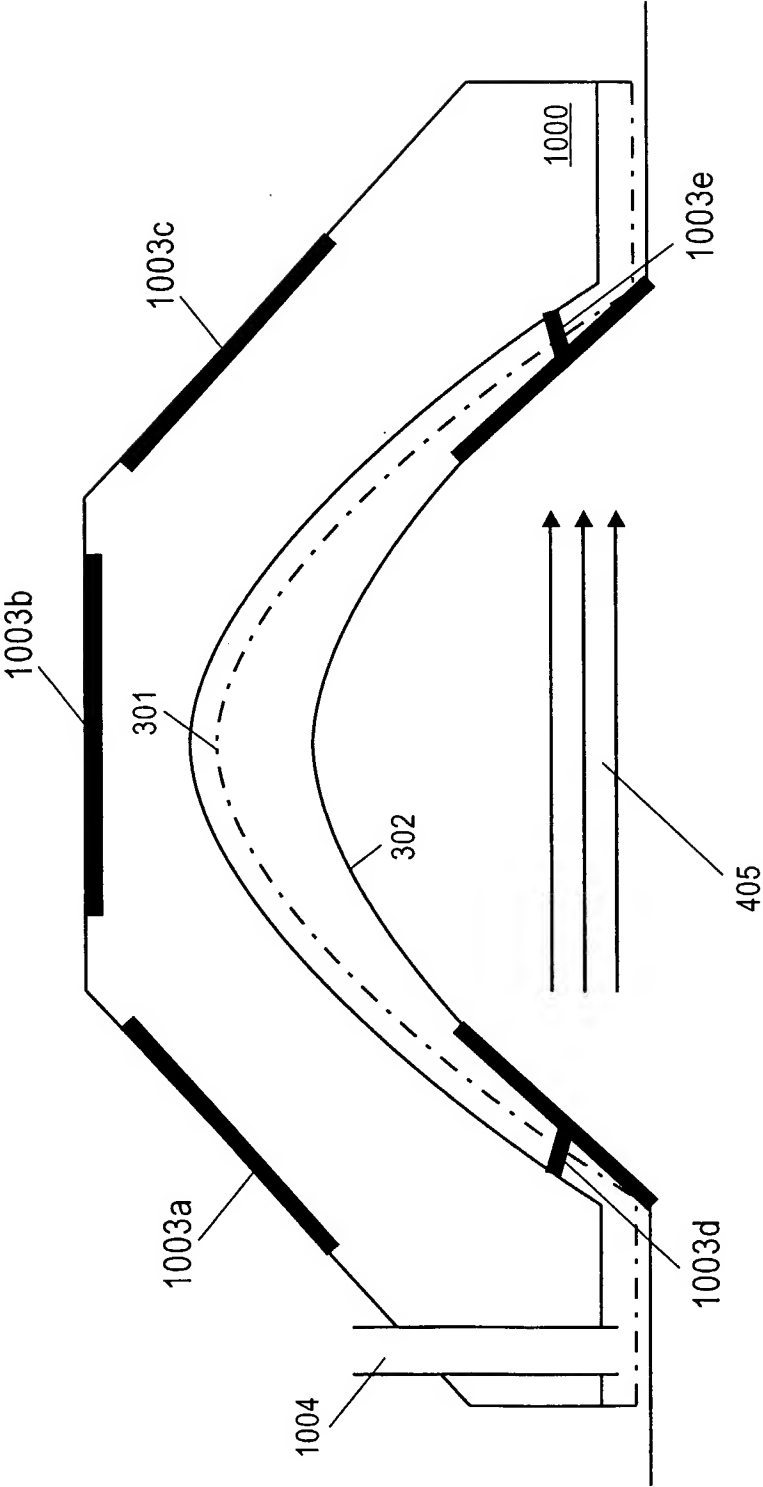


FIG. 10

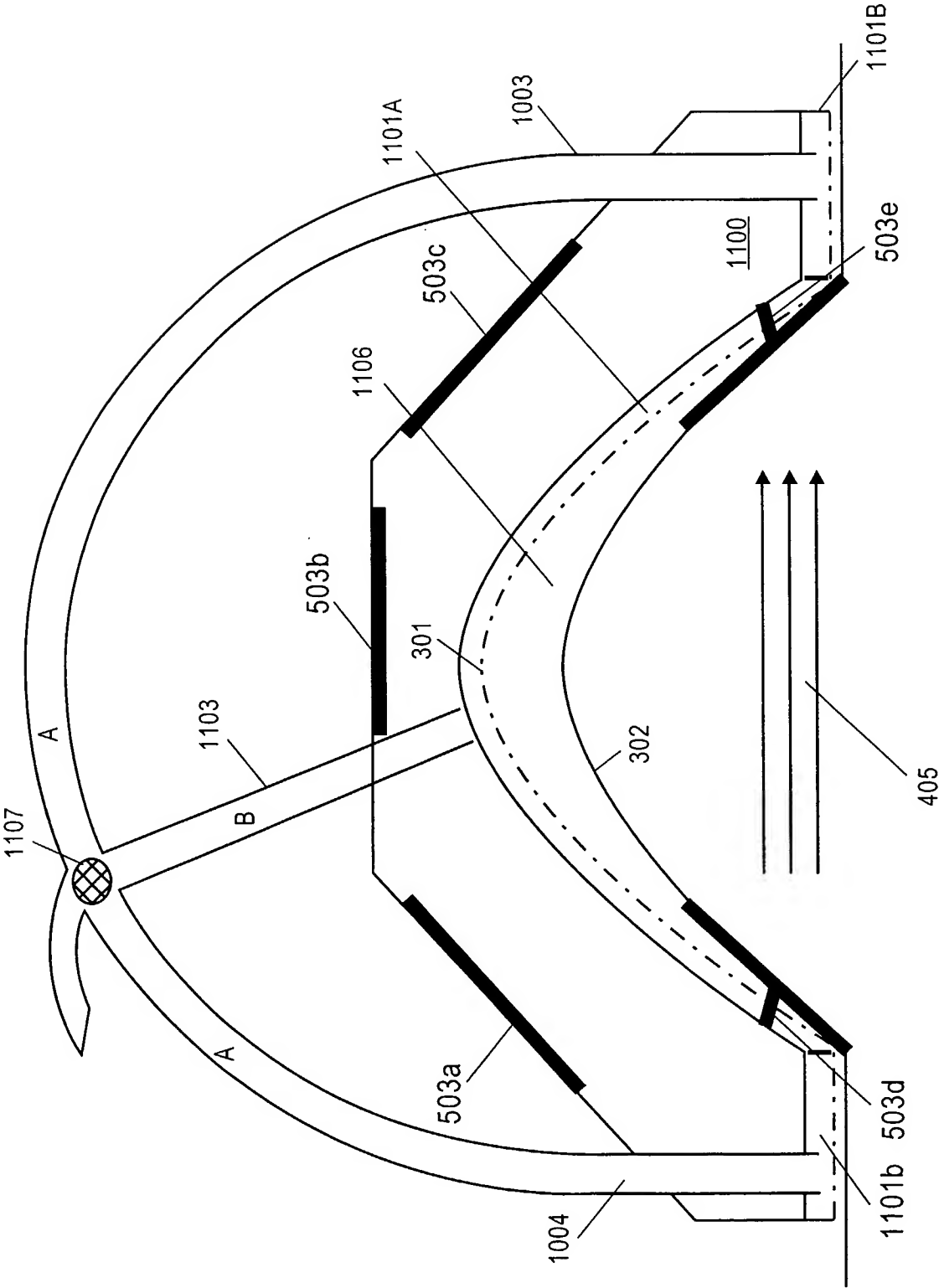
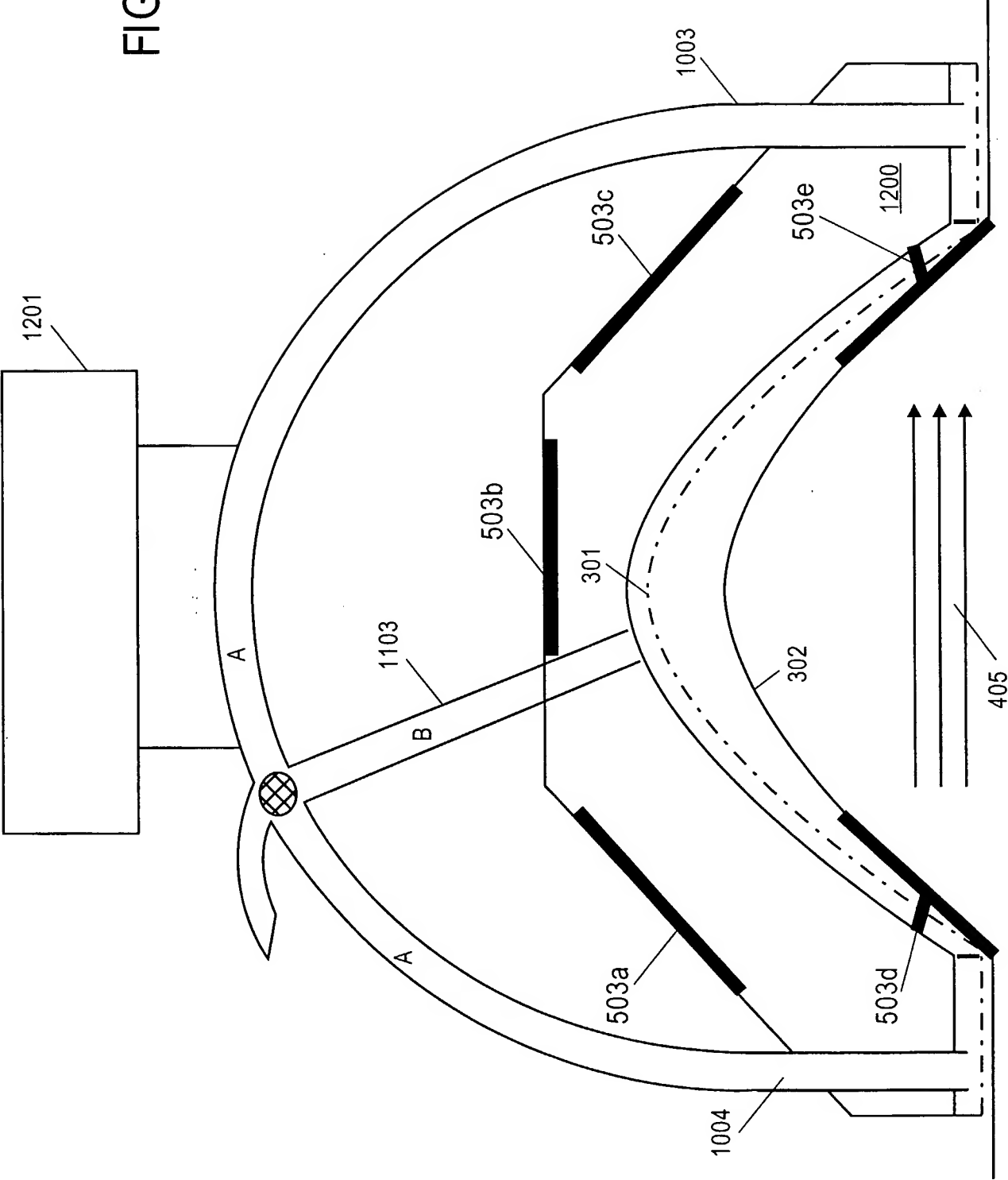


FIG. 11

FIG. 12



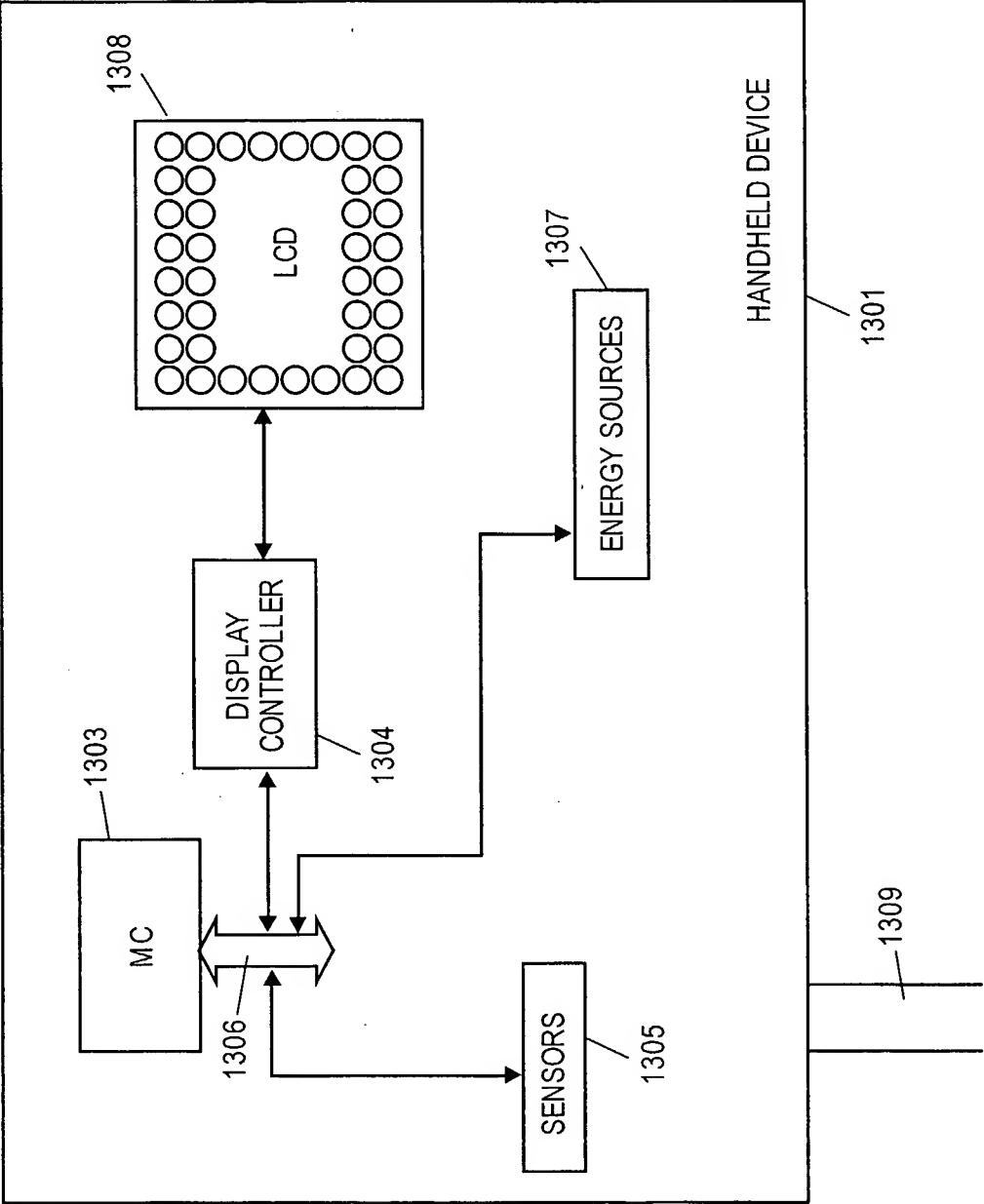
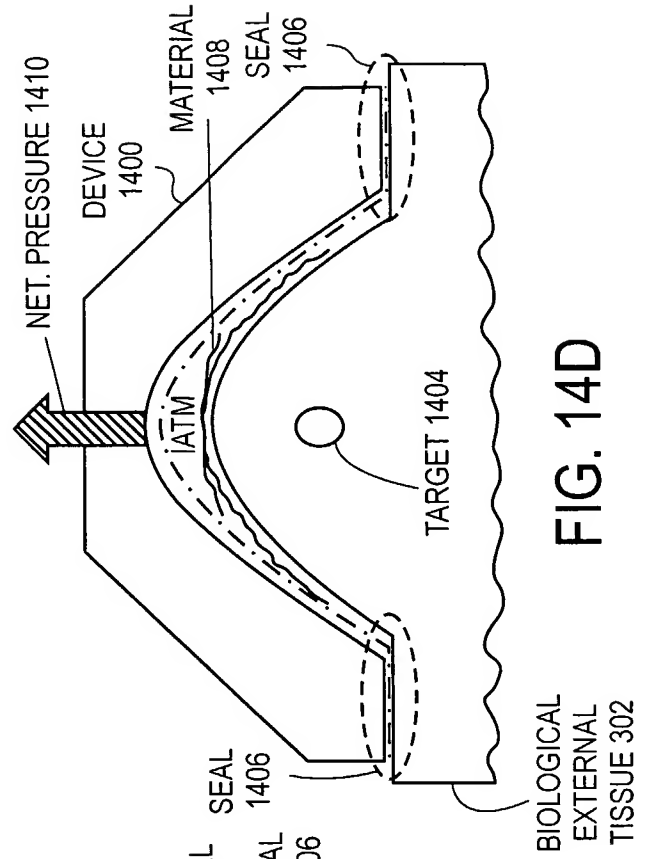
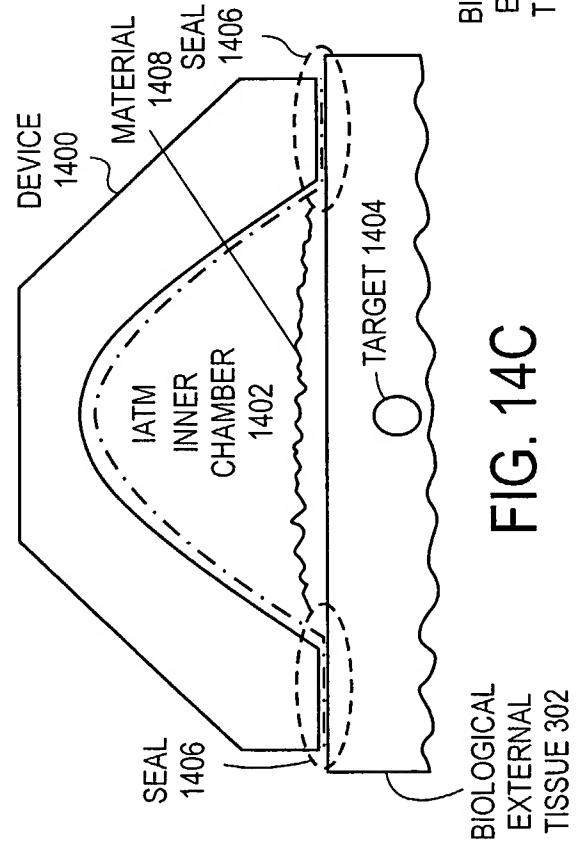
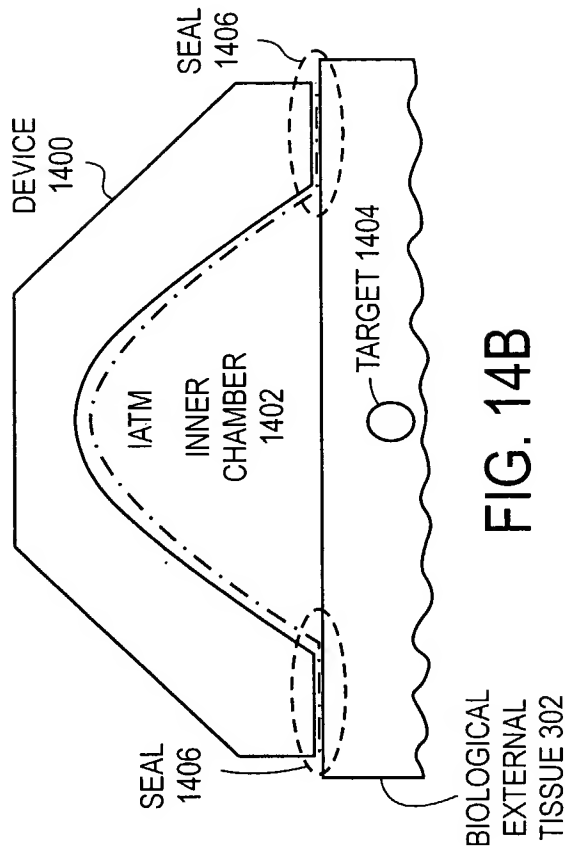
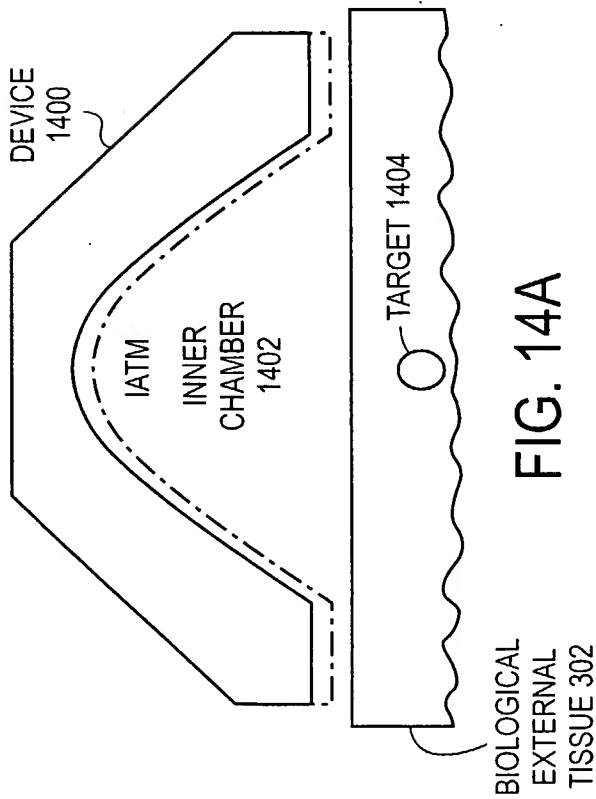
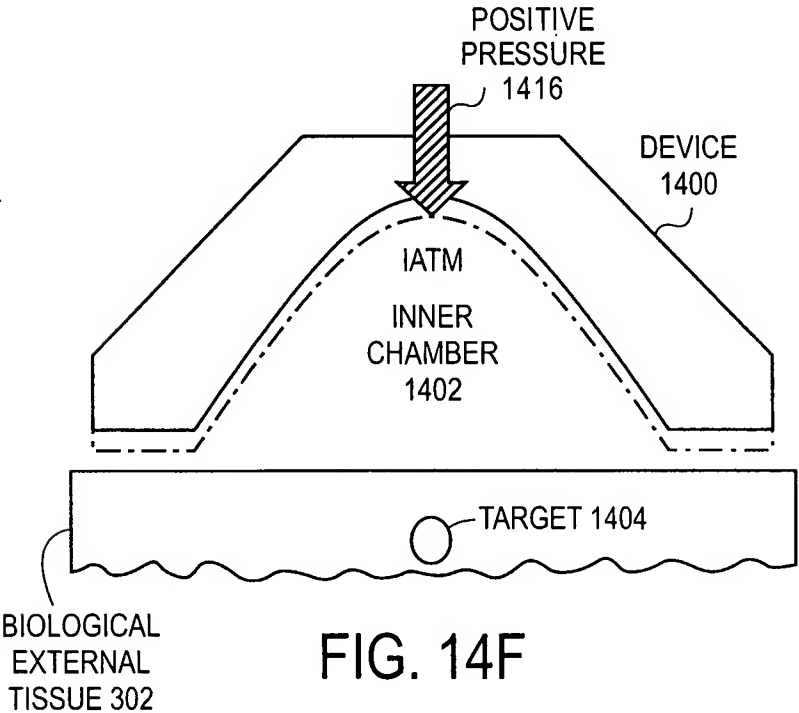
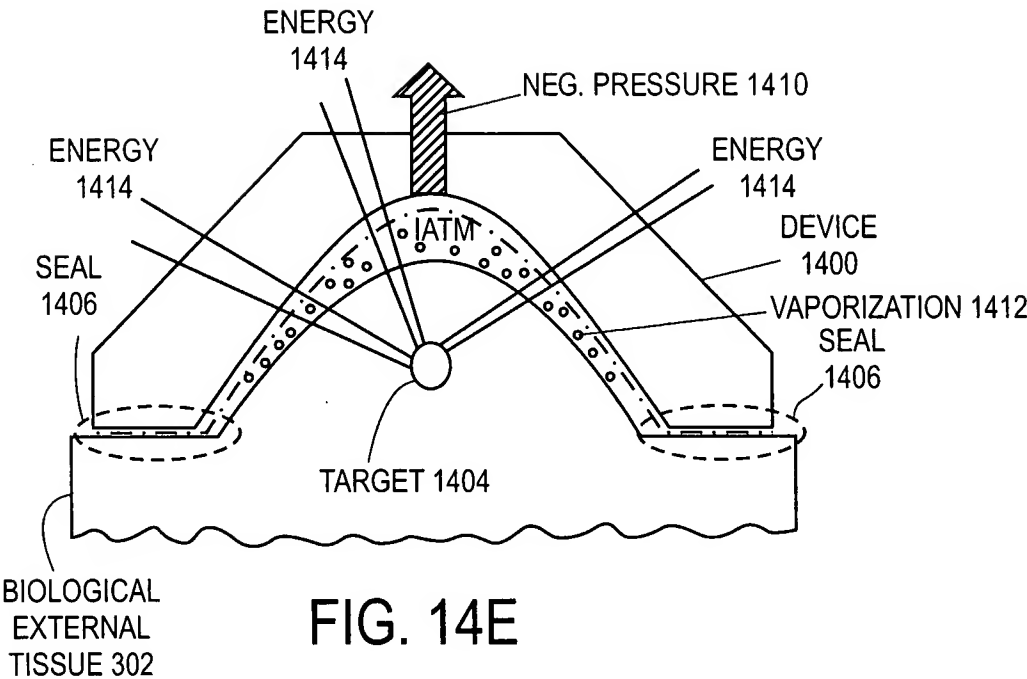


FIG. 13

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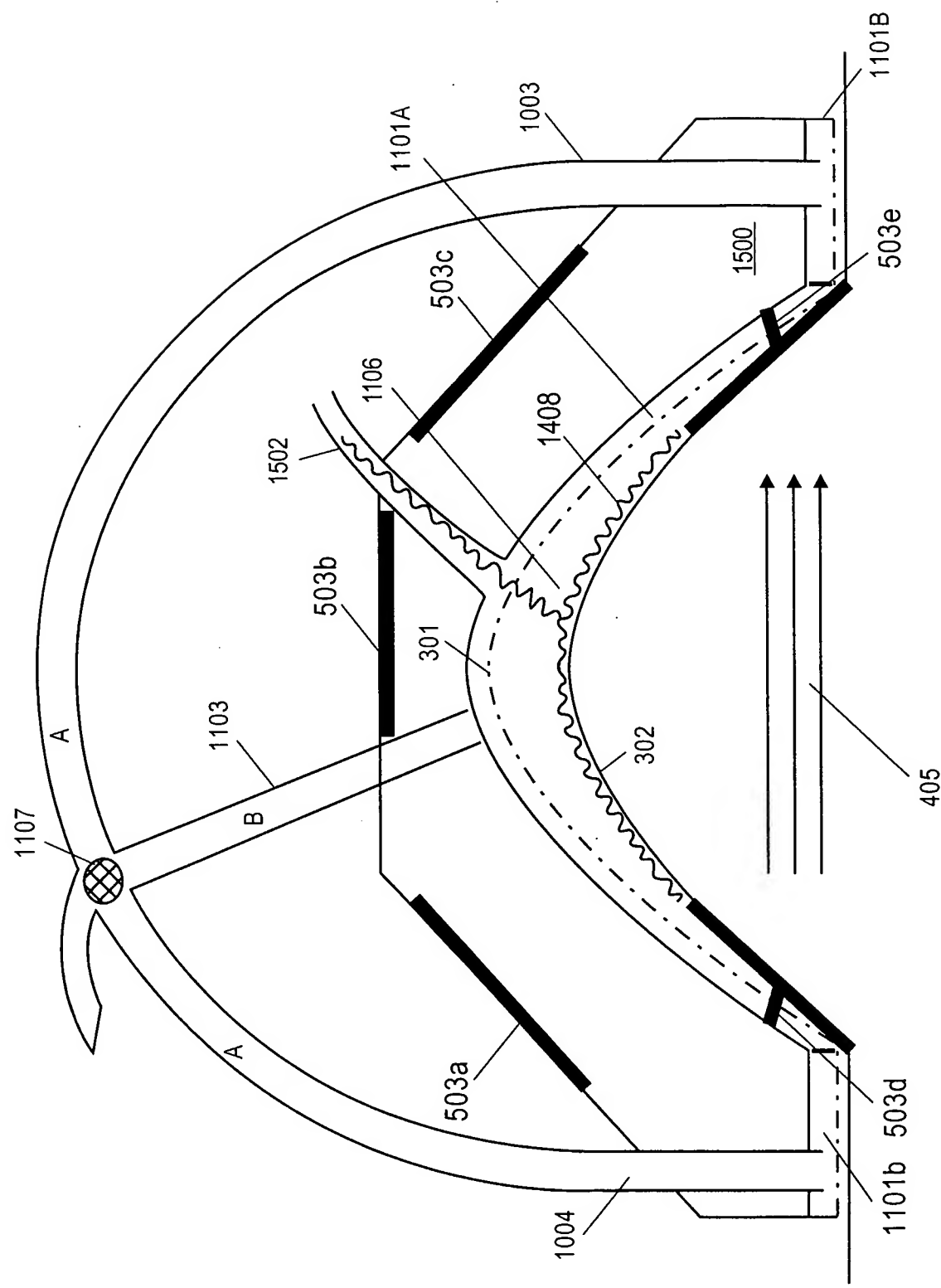


FIG. 15

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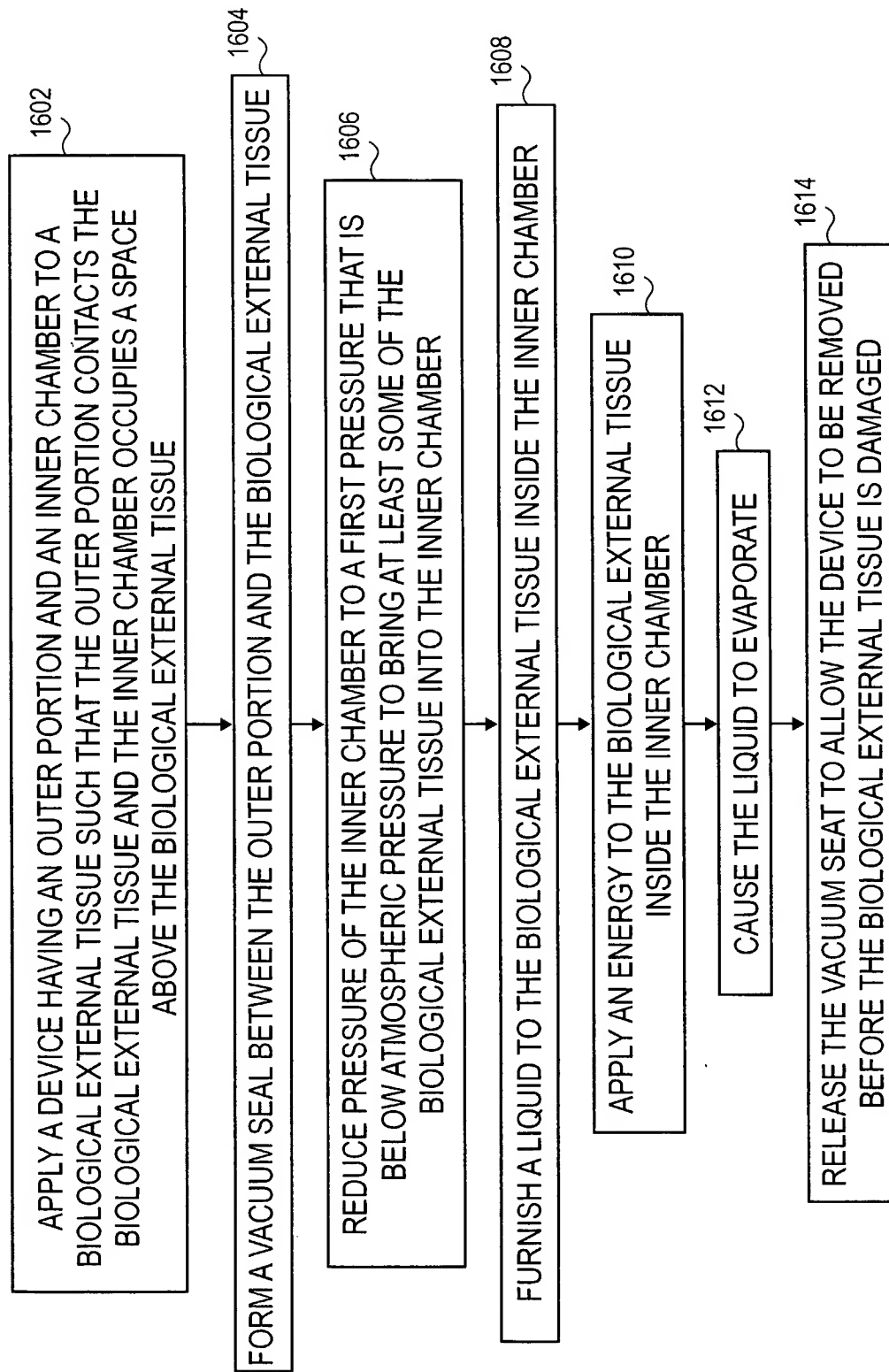


FIG. 16

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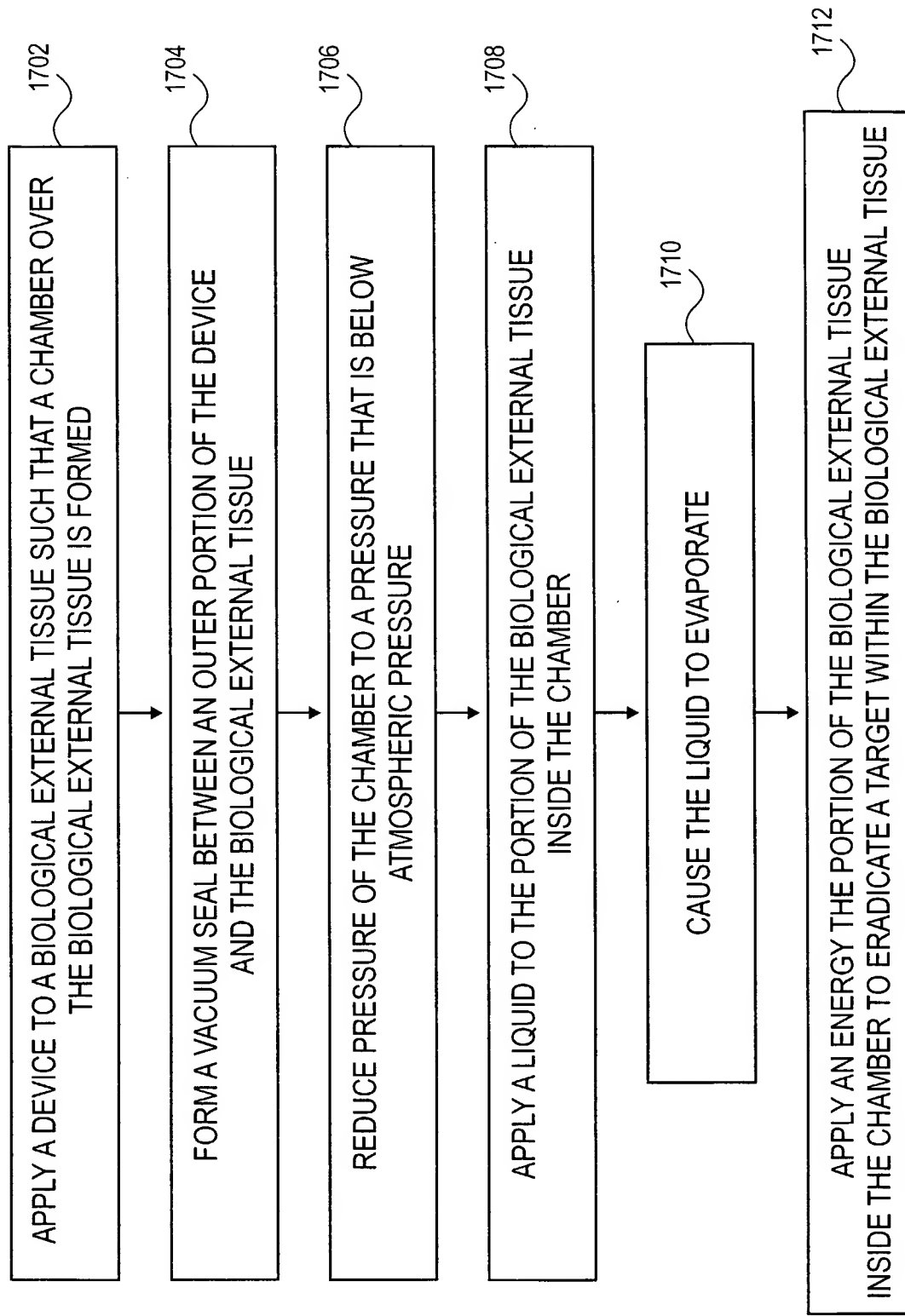


FIG. 17

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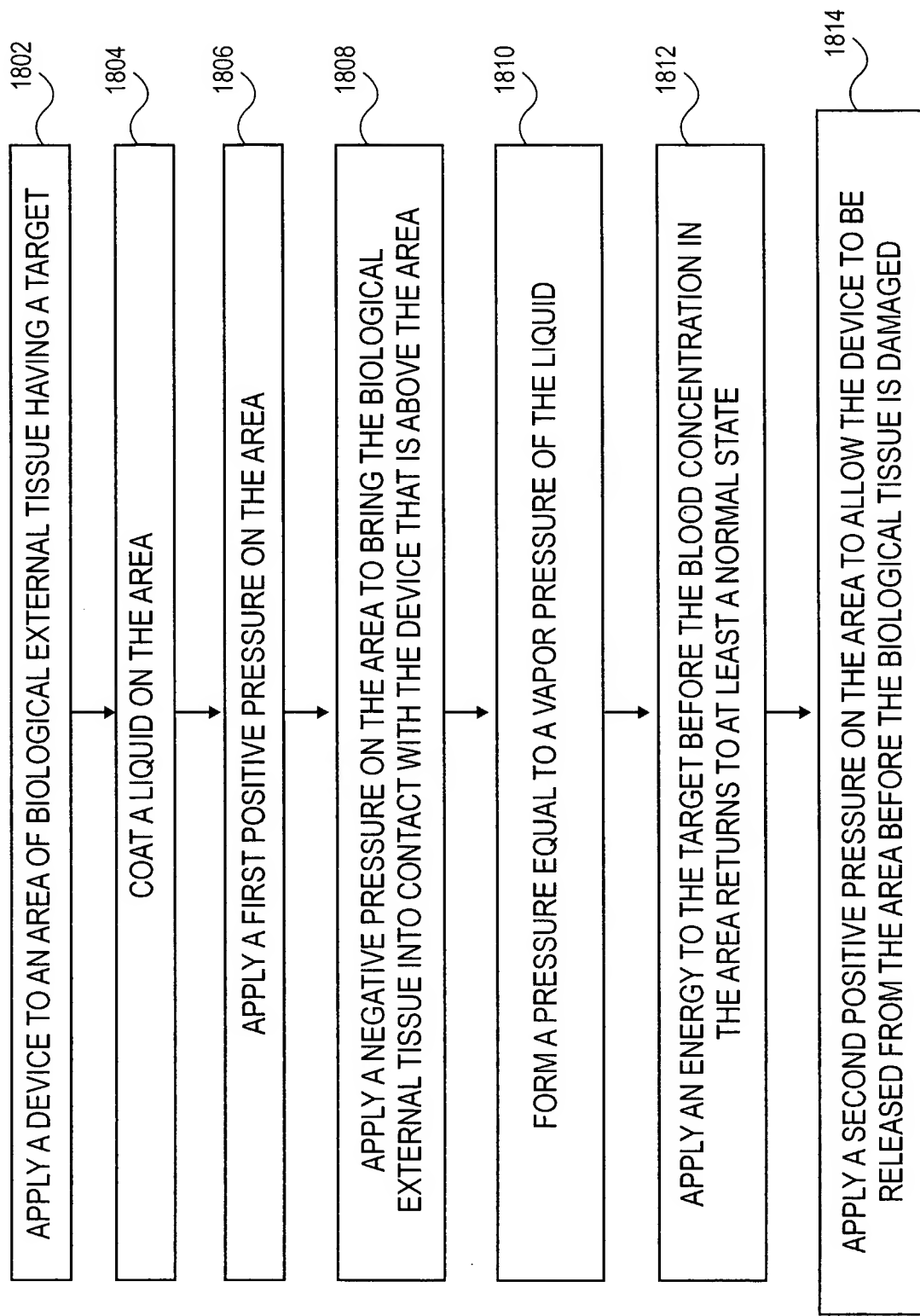


FIG. 18

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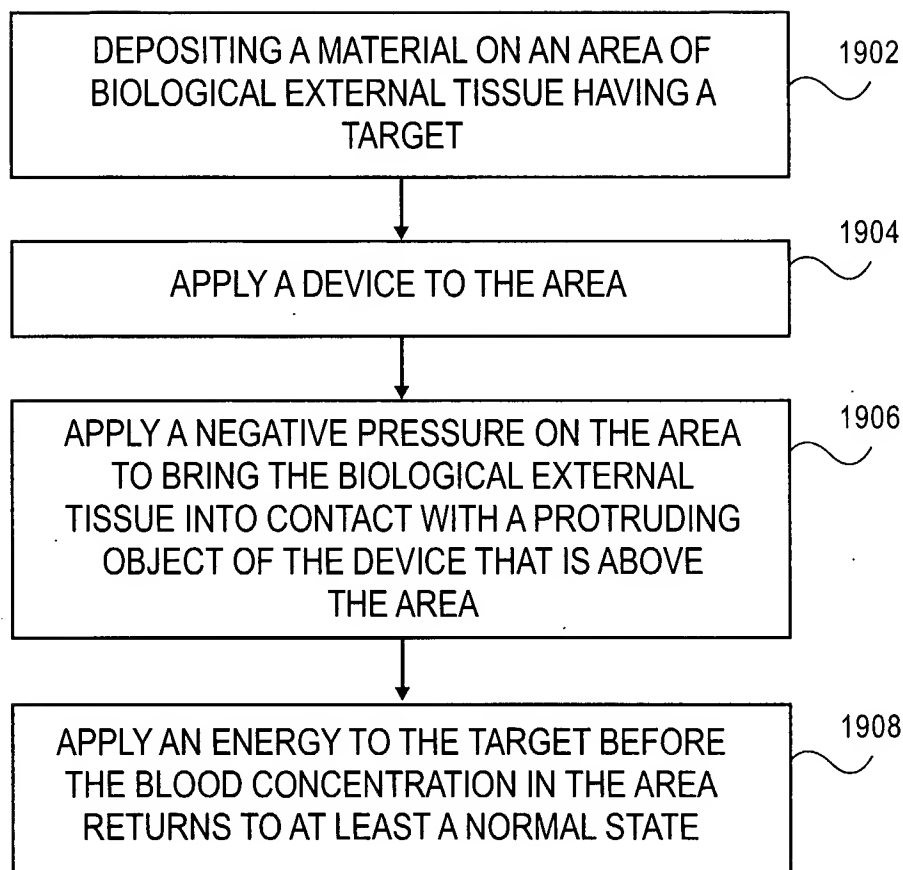


FIG. 19

25/29

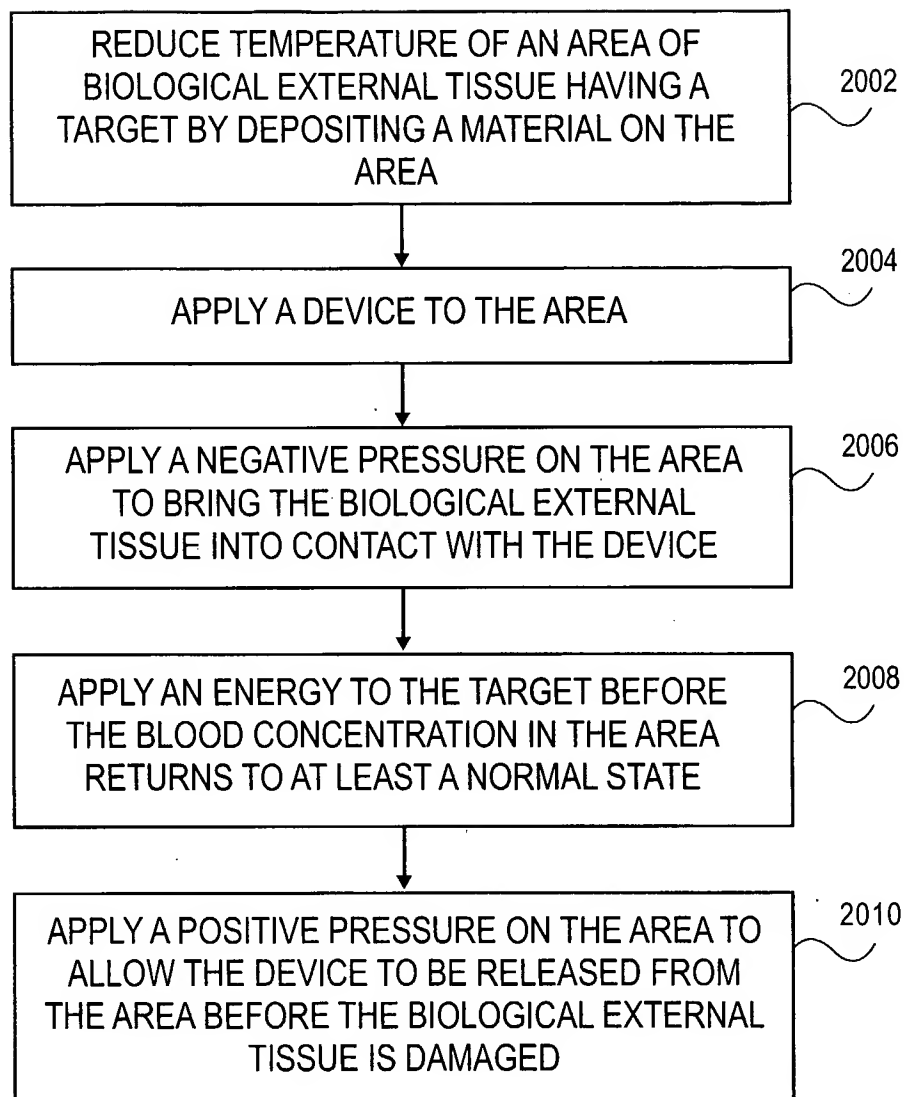


FIG. 20

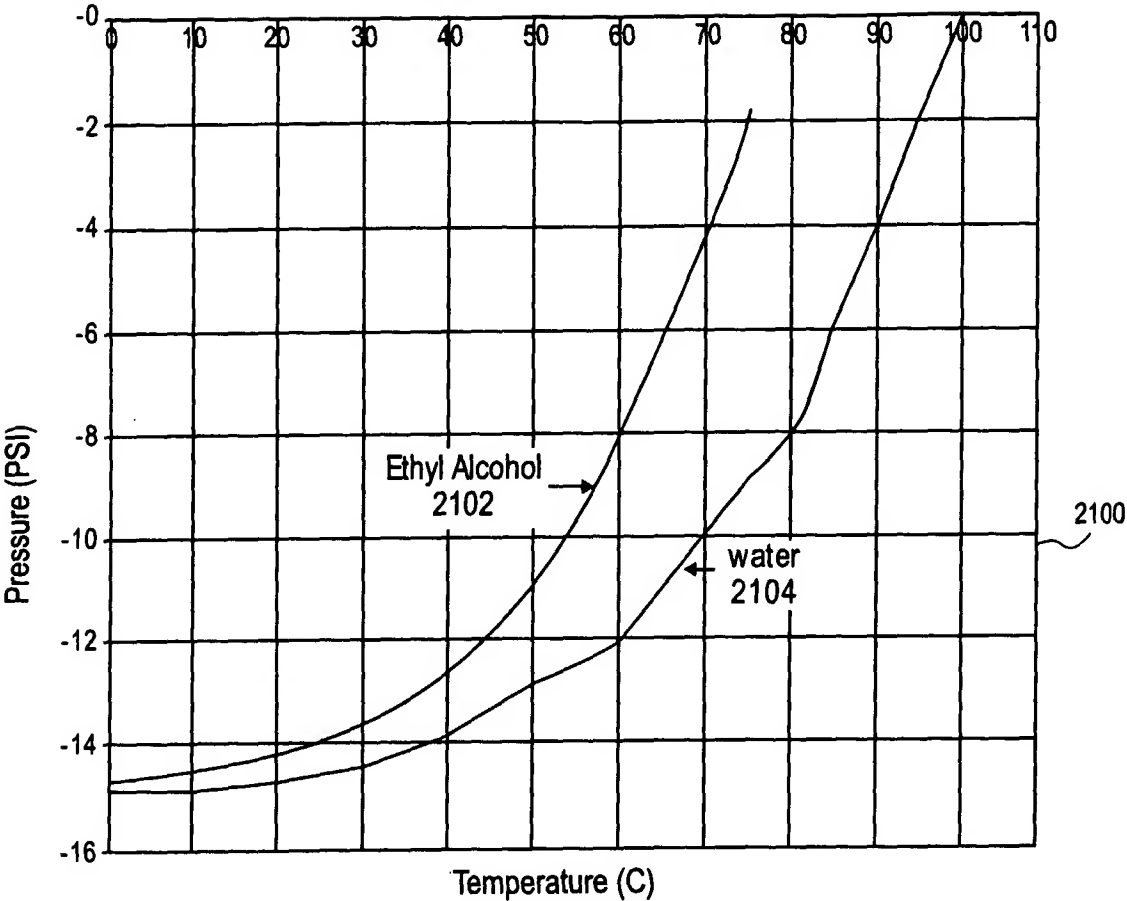
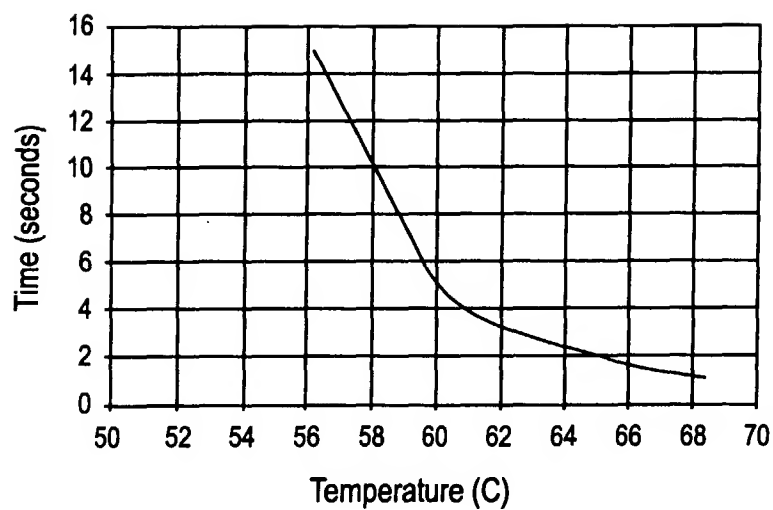


FIG. 21

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Time at temperature to burn biological
external tissue (e.g., skin).

FIG. 22

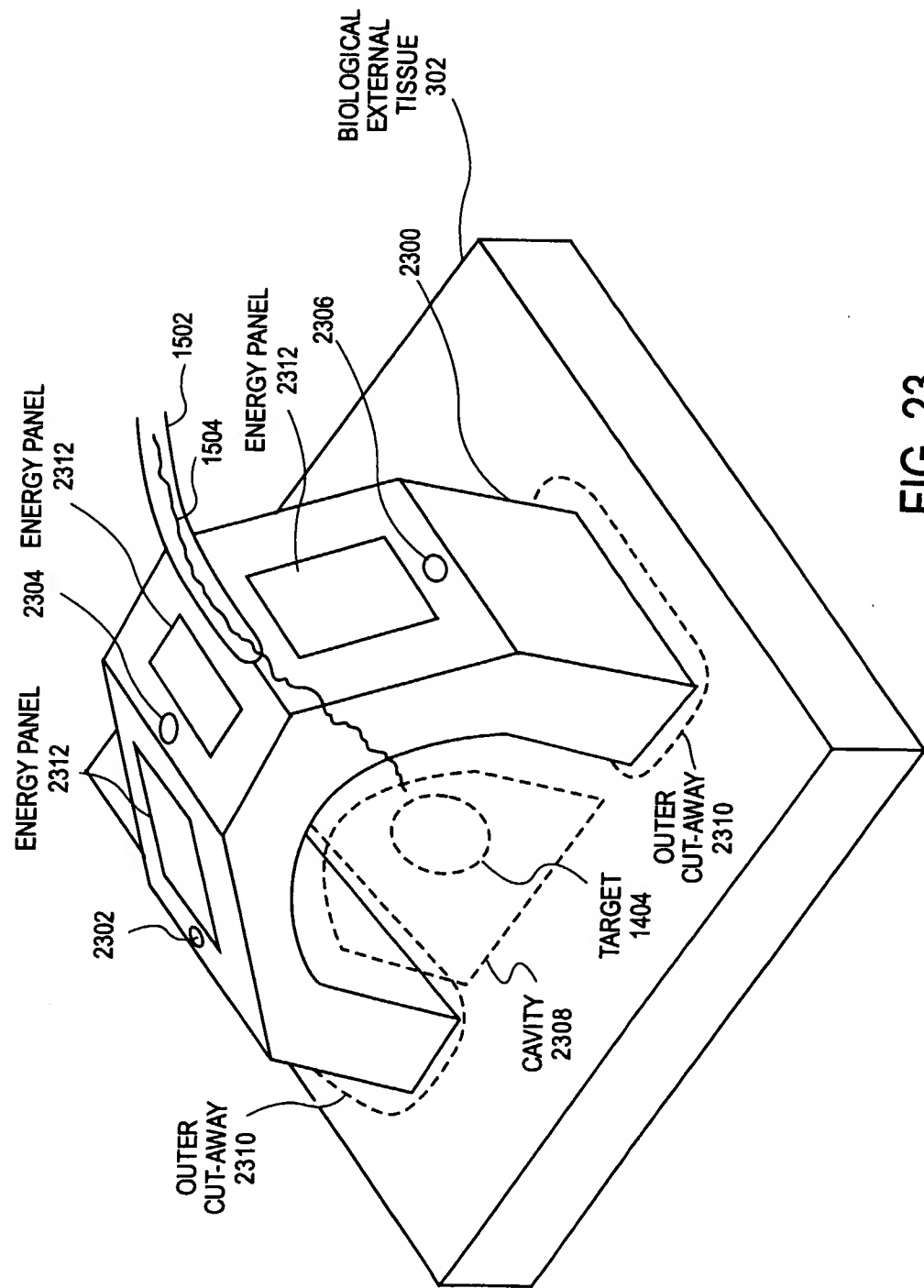


FIG. 23

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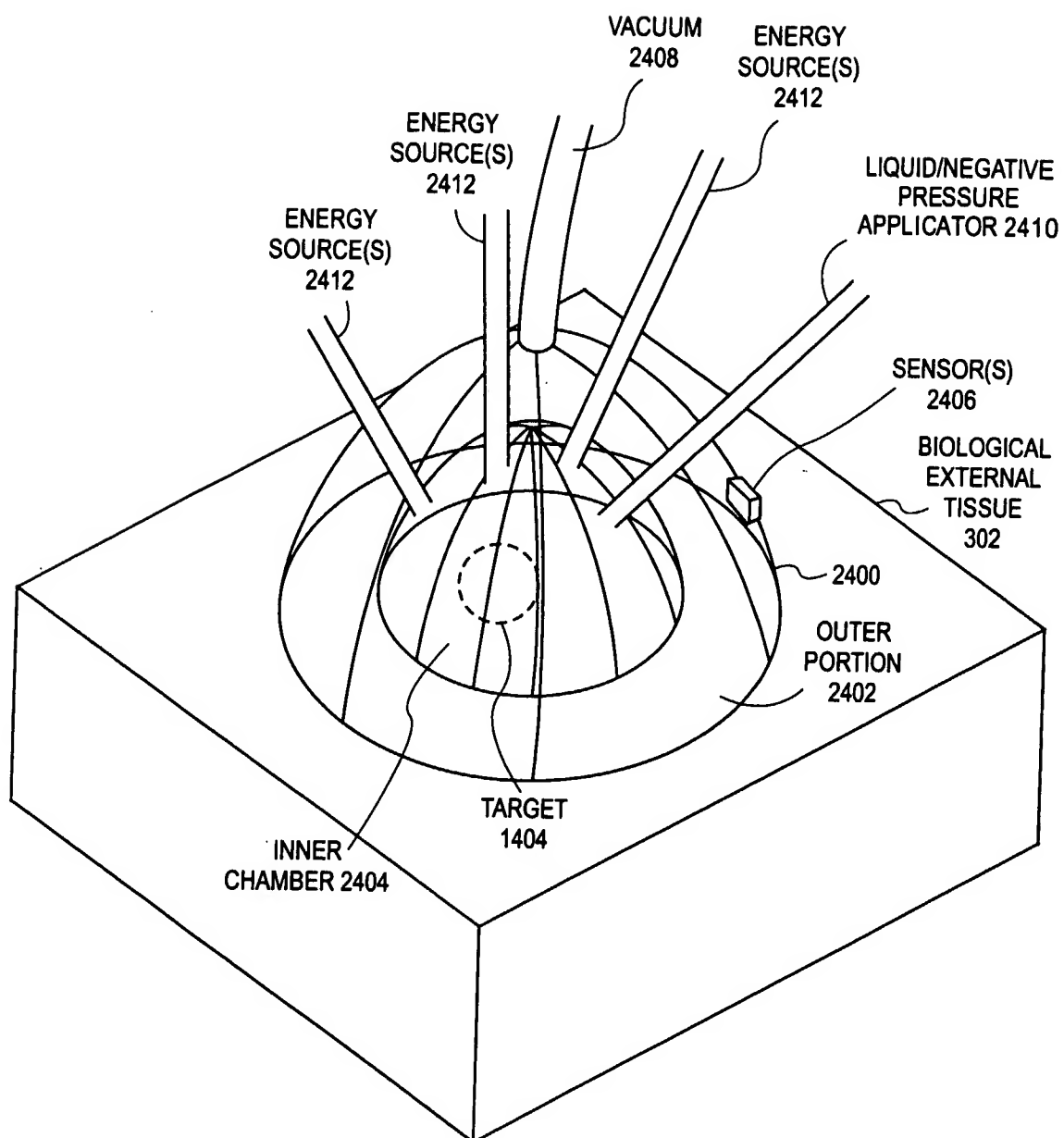


FIG. 24

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/20 A61B18/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 674 031 A (HANS-JOACHIM WEICHE) 4 July 1972 (1972-07-04)	16, 17
Y	column 3, line 43 - column 4, line 30; claim 1	18-26, 38-40
X	WO 03/096919 A (NEEV, JOSEPH) 27 November 2003 (2003-11-27)	38-40
Y	claims 1-10; figures 2-4	16, 17
X	US 3 712 306 A (BRYNE M, US) 23 January 1973 (1973-01-23)	16, 17, 25, 26
Y	claim 1; figure 5	38-40
X	US 3 794 039 A (KOLLNER P, DT ET AL) 26 February 1974 (1974-02-26)	16, 17, 25, 26
Y	the whole document	38-40
	----- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents:

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

11 July 2005

Date of mailing of the international search report

26/07/2005

Name and mailing address of the ISA

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Authorized officer

Chopinard, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/015126

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 862 627 A (HANS, SR. ET AL) 28 January 1975 (1975-01-28) the whole document -----	16-26, 38-40

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US2005/015126

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-15, 27-37
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/015126

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3674031	A	04-07-1972	DE 1916343 A1 CH 522397 A FR 2040113 A5 GB 1271881 A JP 52031674 B	01-10-1970 30-06-1972 15-01-1971 26-04-1972 16-08-1977
WO 03096919	A	27-11-2003	US 2002169442 A1 AU 2003231796 A1 WO 03096919 A1	14-11-2002 02-12-2003 27-11-2003
US 3712306	A	23-01-1973	NONE	
US 3794039	A	26-02-1974	DE 1953835 A1 CH 516304 A FR 2066563 A5	13-05-1971 15-12-1971 06-08-1971
US 3862627	A	28-01-1975	NONE	

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(74) Agents: **ROLFES, Johannes, G., A.** et al.; Prof. Holstlaan 6, NL-5656 AA Eindhoven (NL).

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KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

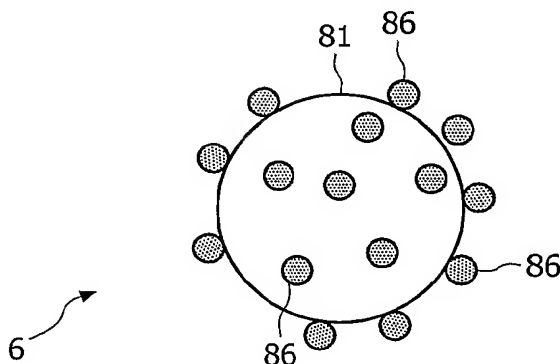
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LIGHT MODULATOR



(57) Abstract: The light modulator for modulating light has a light modulating element, having a medium with a particle (6) and an optical state depending on the position of the particle (6), and a particle controller (10,11,100) being arranged to enable a movement of the particle (6) to one of the positions for modulating the light. For the light modulator to have a particle (6) which can relatively easily be moved, the particle (6) has a carrier particle (81) which contributes in operation to the ability of the particle (6) to be moved and is substantially non-contributing to the optical state, and an optical particle (86) which has an optical property for contributing to the optical state, is associated with the carrier particle (81), and has a position depending on the position of the carrier particle (81).

Light modulator

The invention relates to a light modulator for modulating light.

The invention also relates to a device comprising such a light modulator.

5 A light modulator for modulating light is disclosed in WO 03/071348. The disclosed light modulator is an electrophoretic display panel for generating a colored image. The panel has a pixel having an electrophoretic medium that is substantially transparent in the optical spectral range and cyan particles for absorbing red light, magenta particles for absorbing green light and yellow particles for absorbing blue light. In order for the particles
10 to be transparent for non-absorbed wavelengths, the size of the light absorbing layers/structures in the particle should be well below the internal wavelength of light in the particle, i.e. the wavelength of the light divided by the refractive index of the particle. For this purpose small, nanometer sized, particles can be used. Alternatively a larger, porous, particle with a refractive index matched to the solvent can be used. Light absorption can then
15 be achieved by coating the outside or/and in the pores of the particle with a dye layer that is thinner than the internal wavelength of the light. By moving the particles in/out of a visible area of the pixel by generating electric fields color absorption can be controlled at will and a picture can be displayed. However, it is difficult for the particles to be moved.

20 It is an object of the invention to provide a light modulator of the kind mentioned in the opening paragraph which has a particle which can relatively easily be moved.

25 To achieve this object, the invention provides a light modulator for modulating light comprising

- a light modulating element having
 - a medium comprising a particle, and
 - an optical state depending on a position of the particle, the particle comprising
 - a carrier component contributing in operation to an ability of the particle to be moved

and substantially non-contributing to the optical state, and

- an optical component
 - having an optical property for contributing to the optical state,
 - being associated with the carrier component, and
 - 5 • having a position depending on a position of the carrier component,

- a particle controller being arranged to enable a movement of the particle to one of the positions for modulating the light.

As a consequence of the particle comprising a carrier component which contributes to the ability of the particle to be moved, the particle can relatively easily be moved. Furthermore,
10 the optical state depends on the optical property of the optical component and is substantially independent of the carrier component, as the carrier component is substantially non-contributing to the optical state. As a result, the relatively large ability of the particle to be moved is independent from the optical property of the particle. This is in contrast to the display panel disclosed in WO 03/071348, where the particle does not have a carrier
15 component contributing to the ability of the particle to be moved and where no particle is obtained having a relatively large ability to be moved which is independent from the optical property of the particle.

 If the carrier component comprises a net charge or the carrier component comprises a net magnetic moment, the ability of the carrier component to be moved can
20 relatively easily be tuned. Furthermore, if the carrier component comprises a net charge, the particle controller may comprise electrodes receiving potentials from drive means. Such kind of particle controller can easily be manufactured. Furthermore, if the carrier component comprises a net magnetic moment, the particle controller may comprise a switchable magnet, e.g. a solenoid, which can easily be manufactured. The carrier component comprising both a
25 net charge and a net magnetic moment is also possible. It is also possible that the carrier component may become magnetized or electrically polarized during operation by the presence of the applied magnetic or electric fields. An example of the latter case is a dielectrophoretic system, where polarized particles move along directions of varying field strength under the influence of an applied AC electric field.

30 If the medium comprises a fluid and the refractive index of the carrier component is substantially equal to the refractive index of the fluid for being substantially non-contributing to the optical state, the carrier component can relatively easily be manufactured. Alternatively, the medium comprises a fluid and the carrier component is porous for including part of the fluid inside pores for being substantially non-contributing to

the optical state. Then the number of materials to be used as carrier component is relatively large as the refractive indexes of carrier component and fluid need not match.

In an embodiment the carrier component comprises a carrier particle which is robust and may readily be fabricated. Alternatively, the carrier component comprises a fluid filled capsule. The fluid may be a liquid or gas. The wall of the capsule can comprise polymers, inorganic materials or phospholipid/surfactant (that can optionally be cross-linked).

In another embodiment the optical component is substantially non-contributing to the ability to move, for example is not on the surface.

In another embodiment the optical component comprises an optical film covering at least part of an outer surface of the carrier component. Preferably, the optical film completely covers the outer surface of the carrier component. Then the particle can relatively easily be manufactured. In a variation on the embodiment, the optical component comprises a predetermined number of optical particles, the number being at least one. Such optical particles can readily be obtained with a wide variety of colors. Preferably, each optical particle has a diameter smaller than 500 nm. If, furthermore, the optical particles are attached to an outer surface of the carrier component, then the particles of different colors can be attached to the same type of carrier particle in a straight forward manner. Alternatively, the optical particles are present in the carrier component. Then the particle becomes more robust. If the predetermined number of optical particles is at least two and a portion of the optical particles has an optical property different from an optical property of the other optical particles, then the optical property of the optical component can easily be tuned. In another variation on the embodiment, the optical component comprises a dye. Preferably, the dye is molecularly dissolved in the carrier component. Advantages are that, if the dye is dissolved, it is automatically homogenously distributed throughout the carrier particle. In the case of pigment particles such distribution is more difficult, and the pigment particles may have to be stabilized against aggregation during the fabrication of the carrier particle. Hence: ease of manufacturing. Furthermore, dye molecules are automatically non-scattering, whereas this is more difficult to achieve with pigment particles. Hence, it is much easier to achieve truly transparent carrier particles with dyes. Furthermore, with dissolved dyes, each dye molecule is optically active. In the case of pigment particles, only the surface of the pigment is optically active. Hence, it is easier to achieve the desired optical effect (better color saturation) with less use of material in the case of dyes.

In another embodiment the light modulator comprises a component for elongating the optical path, for example by introducing a forward scattering of the light.

In another embodiment, the light modulator modulates light from an external or internal light source for lighting applications, e.g. a lighting system for lighting a room or
5 a road which has a light output which is adjustable in intensity and/or color and/or direction.

Another aspect of the invention provides a display panel for displaying a picture comprising the light modulator as claimed in claim 1. In an embodiment, the light modulating element comprises a pixel, and the particle controller is arranged to enable a movement of the particle to one of the positions for displaying the picture. In a variation on
10 the embodiment, the display panel is an active matrix display panel.

Another aspect of the invention provides a display device comprising the display panel as claimed in claim 19 and a circuitry to provide image information to the
15 display panel.

These and other aspects of the light modulator of the invention will be further elucidated and described with reference to the drawings, in which:

20 Figure 1 shows diagrammatically a front view of an embodiment of the light modulator;

Figure 2 shows diagrammatically a cross-sectional view along II-II in Figure 1;

Figure 3 shows diagrammatically a carrier particle with small absorbing nano-
25 particles on the surface;

Figure 4A shows diagrammatically a particle having a carrier particle with thin absorbing film on the surface;

Figure 4B shows diagrammatically a particle having a carrier particle having a thin absorbing film inside the carrier particle;

30 Figure 5A shows diagrammatically a particle having a carrier particle with small absorbing nano-particles in the volume of the carrier particle;

Figure 5B shows diagrammatically a particle having a carrier particle and a dye molecularly dissolved in the matrix of the carrier particle;

Figure 6 shows diagrammatically a particle having a carrier particle with small absorbing nano-particles on the surface and in the volume of the carrier particle;

Figures 7A, 7B, 7C, 7D, 7E show examples of particles having fluid filled capsules as carriers for nano-particles or dyes;

Figure 8 shows an example of a size distribution of inkjetted particles, percentage of particle in 1 micron classes is given;

Figure 9 shows an example of a SEM picture of PLA particles;

Figure 10 shows diagrammatically a cross-sectional view along II-II in Figure 1 of another embodiment of the light modulator; and

Figure 11 shows diagrammatically a cross-sectional view along XI-XI in Figure 10.

In all the Figures corresponding parts are referenced to by the same reference numerals.

Figures 1 and 2 show an example of the light modulator being a display panel 1 having a first substrate 8, a second transparent opposed substrate 9 and a plurality of pixels 2. Preferably, the pixels 2 are arranged along substantially straight lines in a two-dimensional structure. Other arrangements of the pixels 2 are alternatively possible, e.g. a honeycomb arrangement. In an active matrix embodiment, the pixels 2 may further comprise switching electronics, for example, thin film transistors (TFTs), diodes, MIM devices or the like.

An electrophoretic medium 5, having first charged particles 6 in a transparent fluid, is present between the substrates 8, 9. The surface 15 of the first substrate 8 facing the second substrate 9 may be transparent, reflective or have any color.

Substrate 8 may even be transparent if the panel 1 is used in light transmissive mode.

Electrophoretic media 5 are known per se from e.g. US 2002/0180688.

The pixel 2 has an optical state depending on the position of the particles 6. Each particle 6 has a carrier component 80 and an optical component 85. The carrier component 80

contributes in operation to the ability of the particle 6 to be moved and is substantially non-contributing to the optical state. The optical component 85 has an optical property for contributing to the optical state, is associated with the carrier component 80, and has a position depending on the position of the carrier component 80. The optical component 85 may have any color, e.g. red, green, blue, cyan, magenta, yellow, white or black. The optical

component 85 may be large enough to scatter light, or small enough to substantially not scatter light.

In an embodiment, the carrier component 80 of the particle 6 is a carrier particle 81 and the optical component 85 of the particle 6 has small absorbing nano-particles 86 which are distributed on the surface of the carrier particle 81. This is illustrated in Figure 3.

Alternatively, the optical component 85 is a thin film 87 with a thickness below the wavelength of visible light, e.g. carrier particles 81 coated with a thin film 87 of the absorbing colors, see Figure 4A. A preferred option is to have a thin film 87 inside the carrier particle 81 (uncolored core – colored film – uncolored shell structure), see Figure 4B. This option allows control of the charging process independently from the color absorption.

In another embodiment, the optical component 85 of the particle 6 has small absorbing nano-particles 86 in the volume of the carrier particle 81. This is illustrated in Figure 5A. This can be realized in the following system by dispersing the nano-particles 86 in the molten host material, dispersing this in droplets of a desired size followed by cooling and solidification. In this case, it is preferred if the nano-particles 86 are distributed with a separation distance sufficient to prevent unwanted optical effects, e.g. backscattering. The ultimate case of this embodiment is when a dye 88 is dissolved on the molecular level in the host matrix of the carrier particle 81, essentially affording a transparent but fully colored particle 6, as shown in Figure 5B.

In another embodiment, the optical component 85 of the particle 6 has small absorbing nano-particles 86 which are distributed both on the surface and in the volume of the carrier particle 81. This is illustrated in Figure 6. The nanoparticles on the surface may also be combined to a thin film. Other combinations are also possible, for example where the particles in the volume of the carrier have a different optical property to the particles or film on the surface.

In another embodiment the carrier component 80 is a fluid filled capsule 82. The capsule wall 83 usually consists of a polymer, inorganic material or (cross-linked) surfactant molecules (single or double layer). Other wall options are also possible. By preparing these capsules 82 in the same medium (liquid or gas) 84 that will later be used for the suspensions, they will exhibit ideal matching of specific gravity, dielectric constant and index of refraction (e.g. the capsules 82 are filled with an alkane and dispersed in the same alkane). By adding a dye 88 to the fluid 84 in which the capsules 82 are prepared, a colored yet transparent entity can be prepared (Figure 7A). Alternatively, it is possible to

embed colored nanoparticles 86 or a dye 88 in the wall of the capsule 83 (Figures 7B and 7C, respectively), or to attach nanoparticles 86 to the outside or inside of the wall 83 (Figures 7D and 7E, respectively), or combinations of these possibilities.

5 Whilst the particles 6 are described with a colored optical component 85, it is also possible that the surface of the carrier component 80 is coated with either a (thin) layer of a luminescent compound (nano-particle 86 or dye 88), or small dots of such a phosphor. In this manner, the efficiency of the phosphor (in the case of particles) may be increased, as the larger surface area results in a larger efficiency.

10 In general, in case of a charged particle 6, it is preferable to have the colored component 85 inside the carrier component 80, since this allows for free choice of the surface chemistry of the particle 6, which is a determining factor for the charge and hence the electrophoretic mobility of the particle 6.

15 In air small optical particles 86 can be used on the surface of larger carrier particles 81, e.g. 10 micron, to stabilize the carrier particles 81 from aggregation. This way free flowing powders can be made. In case the small optical particles 86 are colored and the larger carrier particles 81 are transparent, color displays based on in air concepts are feasible. To have good refractive index matching with the suspension medium, if it is a gas, may be done using highly porous carrier particles 81 or capsules 82.

20 In an alternative preparation method, emulsion procedures common in the preparation of particles 6 (in this case capsules, 82) with biodegradable polymers or lipid shells 83 are used to encapsulate an oil. In the oil dye 88 or colloidal particles 86 can be dispersed. If monodisperse particles (capsules) 6 are desired the preparation method of choice is a drop by drop technique, for instance inkjetting or filtration through a well defined membrane.

25 In general a solution of the shell forming polymer, such as poly-lactic acid, is made in a solvent such as dichloroethane. To this solution a solution of the dye 88 in a fluid 84, for instance oil blue N in tetradecane is added. A small amount of this solution is added to an aqueous PVA solution mechanically stirred or homogenized using other ways common in emulsion preparation.

30 The first mentioned solvent, has a limited solubility in water and will diffuse into the aqueous phase and subsequently evaporate. As the shell forming polymer is not soluble in the oil alone, and not in the aqueous phase, it will be forced to form a shell 83 encapsulating the oil phase 84. The particles (capsules) 6 can be collected, washed and freeze dried to remove remaining volatile solvent leaving fairly rigid spheres that can be redispersed

in preferably the same oil as is present in the interior to minimize the scattering further. The refractive index of the fluid phase 84 inside and outside the particle (capsule) 6 can be matched to that of the shell 83 with a single addition.

The described procedure is effective for all colors, yielding particles (capsules) 6 with the same optical properties, except for their color.

If monodisperse capsules 6 are desired the dye 88 in fluid 84 and the polymer can be mixed and subsequently ink jetted into the PVA solution, for instance using drop on demand ink jetting where the ink jet head is submerged in a solution. By choosing polymer and oil concentration in the starting liquid the size and shell thickness can be set, giving a much better control over the synthesized particles (capsules) 6.

As an example, the preparation of 10 micron PLA particles 6 is described:

A 1% PLA (poly-DL-lactide, Aldrich) solution in dichloroethane was inkjetted, starting immediately after immersion of the ink jet head into an aqueous 1% PVA (15/79) solution in a fluorescence cuvet. The initial drop diameter is about 50 micron as observed through the cuvet which corresponds to a drop volume of $6.5 \times 10^{-14} \text{ m}^3$. After inkjetting for 20 minutes at 1500 Hz, the procedure was stopped. The sediment was redispersed and transferred to a glass sample bottle and stirred for one hour to remove the dichloroethane. The particles were washed 3 times with filtered (200 nm), deionised water. A sample was taken for microscopic examination, revealing well dispersed spherical particles with a diameter of about 10 micron. The size distribution of the mean diameter is given in Figure 8. The sample was freeze dried for 48 hours and stored at -20°C . SEM pictures, taken after redispersion in filtered deionised water, drying and deposition of a 3 nm Pd/Pt layer, show a particle size of 10.2 ± 0.3 micron which corresponds to a particle volume of $5.6 \times 10^{-16} \text{ m}^3$. As the densities of dichloroethane and PLA are approximately equal, the volume ratio between initial and final size demonstrates that PLA particles have been prepared with a low porosity. A SEM picture of the particles produced is given in Figure 9.

As another example, the preparation of 18 micron PLA particles by continuous inkjet is described:

The 1% solution of PLA in dichloroethane was purged at 3 m/s through a 50 micron capillary in a 1% PVA solution, subjected to a piezo frequency of 14 kHz, which causes the jet to break up in droplet with a diameter of about 65 micron. Dichloroethane was removed by stirring for 4 hours and the excess PVA was removed by repeated washing. The particle size distribution is bimodal. The fraction of fines was largely removed by four sedimentation steps. Particles with a narrow size distribution were formed.

As another example, the preparation of oil and dye filled capsules is described: A solution of oil blue N in tetradecane was made and mixed with a 0.5% solution of PLGA (polylactic-co-glycolic acid) in dichloroethane. This solution was added to a 1% PVA solution in water and subjected to stirring for 1 hour. Remaining dichloroethane was removed by slowly stirring for another 4 hours and the excess PVA was removed by three washing steps. Dye containing capsules were formed.

Referring to the display panel 1 of Figures 1 and 2 the particles 6 are able to occupy positions in the pixel 2. The pixel 2 has a viewing surface 91 for being viewed by a viewer. The optical state of a pixel 2 depends on the position of the particles 6 in the pixel 2.

In transmissive mode, the optical state of the pixel 2 is determined by the portion of the visible spectrum incident on the pixel 2 at the side 92 of the first substrate 8 that survives the cumulative effect of traversing through the first substrate 8, medium 5 and the second substrate 9. In reflective mode, the optical state of the pixel 2 is determined by the portion of the visible spectrum incident on the pixel 2 at the side of the second substrate 9 that survives the cumulative effect of traversing through the second substrate 9, medium 5, subsequently interacting with surface 15 of the first substrate 8 which may be reflective or have any color and subsequently traversing back through medium 5 and the second substrate 9.

The amount and color of the light transmitted by medium 5 is controlled by the position and the color of the particles 6. When the particles are positioned in the path of the light that enters the pixel, the particles absorb or scatter a selected portion of the light and the remaining light is transmitted. When the particles are substantially removed from the path of the light entering the pixel, the light can pass through the pixel and emerge without significant visible change. The light seen by the viewer, therefore, depends on the distribution of particles 6 in the pixel.

The particle controller having electrodes 10,11 for receiving potentials from drive means 100 is arranged to enable a movement of the particles 6 to one of the positions for displaying the picture. In this case, each one of the electrodes 10,11 has a substantially flat surface 110,111 facing the particles 6. As a result, a substantially homogeneous electric fields can be generated between the electrodes 10,11.

In an example, consider the particles 6 to be positively charged and black. Furthermore, the fluid is transparent. Consider the pixel layout of Figure 2 and the display panel being used in light transmissive mode. The optical state of the pixel 2 is determined by the portion of the visible spectrum incident on the pixel 2 at the entrance window 92 that

survives the cumulative effect of traversing through the first substrate 8, medium 5 and the second substrate 9 and exits through exit window 91. Consider white light e.g. generated by a (back)light source (not drawn), incident on the entrance window 92.

5 To obtain an optical state being black the particles 6 are brought in their distributed state in the pixel 2 by appropriately changing the potentials received by the electrodes 10,11. As the white light from the light source incident on the pixel 2 is absorbed by the black particles 6, the optical state of the pixel 2 is black.

10 To obtain an optical state being white the particles 6 are brought in their collected state near the surface of electrode 10 or 11, by appropriately changing the potentials received by the electrodes 10,11. The movement of the particles 6 has a component in the plane parallel to the exit window 91 and the particles 6 are brought substantially outside the light path.

Therefore, the white light from the light source is transmitted through the pixel 2 and the optical state of the pixel 2 is white.

15 Intermediate optical states are also possible by appropriately changing the potentials received by the electrodes 10,11. In an example, only a small number of particles 6 are distributed in the pixel 2 thereby not fully absorbing the white light from the light source incident on the pixel 2, which results in an optical state being intermediate between black and white. Further colored optical states can be realized by adding a passive color changing component to the optical system (color filter element, colored liquid, colored reflector etc.).

20 Figures 10 and 11 show another embodiment of the display panel 1. The electrophoretic medium 5 has first, second, third and fourth charged particles 6,7,60,70 in a transparent fluid. Each one of the particles 6,7,60,70 has a carrier component 80 and an optical component 85, respectively. The optical components 85 are small absorbing nanoparticles 86. Consider the first particles 6 to be positively charged, magnetic and to have a yellow color in transmission, the second particles 7 to be positively charged, non-magnetic and to have a cyan color in transmission, the third particles 60 to be negatively charged, magnetic and to have a magenta color in transmission, and the fourth particles 70 to be negatively charged, non-magnetic and to have a black color. Furthermore, each one of the electrodes 10,11,15 has a substantially flat surface 110,111,115 facing the particles 6,7,60,70 and the viewing surface 91. Furthermore, the surfaces 110,111,115 of the electrodes 10,11,15 are present in a substantially flat plane. The region near the surface 110 of electrode 10 provides a first reservoir for the yellow and cyan particles 6,7 and is substantially non-contributing to the optical state of the pixel 2. This is achieved by a black matrix layer 513 between electrode 10 and the observer. The region near the surface 111 of electrode 11

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provides a second reservoir for the magenta and black particles 60,70 and is substantially non-contributing to the optical state of the pixel 2. This is also achieved by a black matrix layer 513 between electrode 11 and the observer. The position of the particles 6,7,60,70 and the surface 115 of electrode 15 determine the optical state of the pixel 2. Consider the surface
5 115 of electrode 15 to be white. The three electrodes 10,11,15 each incorporate a magnetic sheet, preferably with a vertical anisotropy (a Co/Pt or Co/Cr multilayer magnet would be a good electrode material). This has the effect of creating an extra force for holding the magnetic particles on the electrodes. In this embodiment the display panel 1 is used in light reflective mode.

10 It is furthermore assumed that if an electric field is created between the central electrode 15 and one of the side- electrodes 10,11 that the electric field created with a potential of ± 5 Volts is sufficient to displace only the nonmagnetic particles from the electrodes and that an electric field created with ± 10 Volts is sufficient to displace both nonmagnetic and magnetic particles i.e. this electric field creates sufficient electrostatic force to outweigh the magnetic
15 attraction between magnetic particles and the magnetic electrode.

The process of obtaining different colors is now considered. The first action before displaying a new color is to reset the pixel 2: the yellow and the cyan particles 6,7 are brought into the first reservoir and the magenta and the black particles 60,70 are brought into the second reservoir, by appropriately changing the potentials received by the electrodes
20 10,11,15, e.g. the electrodes 10,11,15 receive -10 Volts, 10 Volts and 0 Volts, respectively. The positively charged particles 6,7 are attracted towards side electrode 10 whereas the negatively charged particles 60,70 are attracted towards side electrode 11, independent of magnetic properties.

Obtaining a color associated with one of the non-magnetic particles 7,70 is the most simple
25 and is now described. To obtain an optical state being cyan the potential of the central electrode 115 is switched to -5 Volts and the electrode 10 from which cyan has to be attracted is set to 0 Volts. At the same time the opposite side-electrode 11 (from which no particles are required) is set to the central electrode potential of -5 Volts. Due to the magnetic attraction between the side-electrodes 10,11 and the magnetic particles 6,60, respectively, the
30 electric field is insufficient to switch either the yellow or magenta particles 6,60.

To obtain an optical state being black the potential of the central electrode 115 is switched to 5 Volts and the electrode 11 from which black has to be attracted is set to 0 Volts. At the same time the opposite side-electrode 10 (from which no particles are required) is set to the central electrode potential of 5 Volts. Due to the magnetic attraction between the side-

electrodes 10,11 and the magnetic particles 6,60, respectively the electric field is insufficient to switch either the yellow or magenta particles 6,60.

In order to obtain a color associated with one of the magnetic particles 6,60 a slightly more complicated driving scheme is required. To obtain an optical state being yellow, the central electrode 15 receives a potential of -10 Volts. The side-electrode 10 from where the yellow particles 6 are sourced is held at 0 Volts and the other side-electrode 11 has the same potential as the central electrode, being -10 Volts. This creates an electric field that is sufficient to switch both the magnetic yellow and the nonmagnetic cyan particles 6,7 to the central electrode 15. This results in a pixel with a green color. In a following step, the electrodes 10,11,15 receive potentials of -5 Volts, 0 Volts and 0 Volts. By doing this the non magnetic cyan particles 7 are returned to the side electrode 10 leaving the magnetic yellow particles 6 on the central electrode 15.

To obtain an optical state being magenta, the central electrode 15 receives a potential of 10 Volts. The side-electrode 11 from where the magenta particles 60 are sourced is held at 0 Volts and the other side-electrode 10 has the same potential as the central electrode, being 10 Volts. This creates an electric field that is sufficient to switch both the magnetic magenta and the nonmagnetic black particles 60,70 to the central electrode 15. Then the electrodes 10,11,15 receive potentials of 0 Volts, 5 Volts and 0 Volts. By doing this the non magnetic black particles 70 are returned to the side electrode 11 leaving the magnetic magenta particles 60 on the central electrode 15.

Furthermore, the optical state of the pixel is green when only the yellow and cyan particles 6,7 are on the central electrode 15; the optical state of the pixel is blue when only the cyan and magenta particles 7,60 are on the central electrode 15; the optical state of the pixel is red when only the yellow and magenta particles 6,60 are on the central electrode 15, and the optical state of the pixel is white when no particles 6,7,60,70 are on the central electrode 15. In this way a 4 particle electrophoretic pixel 2 is envisaged with a magnetic sorting mechanism. Different intensity levels can be obtained by tuning the values of the potentials applied to the electrodes 10,11,15.

The mere fact that certain measures are mentioned in different claims does not indicate that a combination of these measures cannot be used to advantage.

CLAIMS:

1. A light modulator for modulating light comprising
 - a light modulating element having
 - a medium (5) comprising a particle (6), and
 - an optical state depending on a position of the particle (6), the particle (6) comprising
 - 5 ▪ a carrier component (80) contributing in operation to an ability of the particle (6) to be moved and substantially non-contributing to the optical state, and
 - an optical component (85)
 - having an optical property for contributing to the optical state,
 - being associated with the carrier component (80), and
 - 10 • having a position depending on a position of the carrier component (80),
 - a particle controller (10,11,100) being arranged to enable a movement of the particle (6) to one of the positions for modulating the light.
2. A light modulator as claimed in claim 1 characterized in that the carrier
- 15 component (80) comprises a net charge.
3. A light modulator as claimed in claim 1 characterized in that the carrier
- component (80) comprises a net magnetic moment.
- 20 4. A light modulator as claimed in claim 1 characterized in that the medium (5) comprises a fluid and the refractive index of the carrier component (80) is substantially equal to the refractive index of the fluid for being substantially non-contributing to the optical state.
5. A light modulator as claimed in claim 1 characterized in that the medium (5)
- 25 comprises a fluid and the carrier component (80) is porous for including part of the fluid inside pores for being substantially non-contributing to the optical state.
6. A light modulator as claimed in claim 1 characterized in that the carrier
- component (80) comprises a carrier particle (81).

7. A light modulator as claimed in claim 1 characterized in that the carrier component (80) comprises a fluid filled capsule.
- 5 8. A light modulator as claimed in claim 1 characterized in that the optical component (85) is substantially non-contributing to the ability to move.
9. A light modulator as claimed in claim 1 characterized in that the optical component (85) comprises an optical film (87) covering at least part of an outer surface of the
10 carrier component (80).
10. A light modulator as claimed in claim 9 characterized in that the optical film (87) completely covers the outer surface of the carrier component (80).
- 15 11. A light modulator as claimed in claim 1 characterized in that the optical component (85) comprises a predetermined number of optical particles (86), the number being at least one.
12. A light modulator as claimed in claim 11 characterized in that each optical
20 particle (86) has a diameter smaller than 500 nm.
13. A light modulator as claimed in claim 11 characterized in that the optical particles (86) are attached to an outer surface of the carrier component (80).
- 25 14. A light modulator as claimed in claim 11 characterized in that the optical particles (86) are present in the carrier component (80).
15. A light modulator as claimed in claim 11 characterized in that the predetermined number of optical particles (86) is at least two and a portion of the optical
30 particles (86) has an optical property different from an optical property of the other optical particles (86).
16. A light modulator as claimed in claim 1 characterized in that the optical component (85) comprises a dye (88).

17. A light modulator as claimed in claim 16 characterized in that the dye (88) is molecularly dissolved in the carrier component (80).

5 18. A light modulator as claimed in claim 1 characterized in that the light modulator comprises a component for elongating the optical path.

19. A display panel (1) for displaying a picture comprising the light modulator as claimed in claim 1.

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20. A display device comprising the display panel (1) as claimed in claim 19 and a circuitry to provide image information to the display panel (1).

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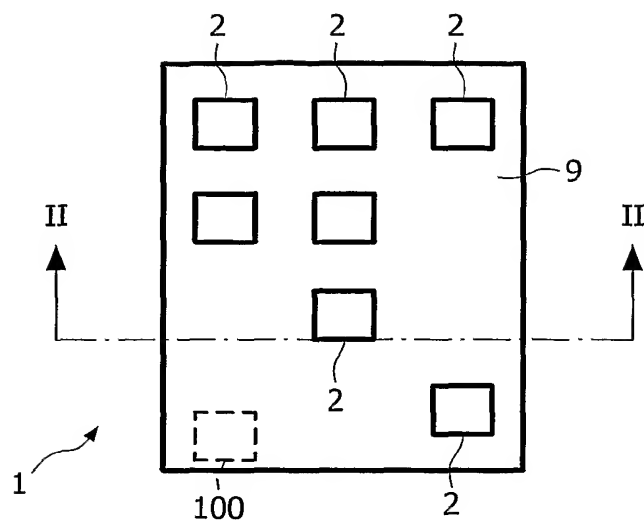


FIG. 1

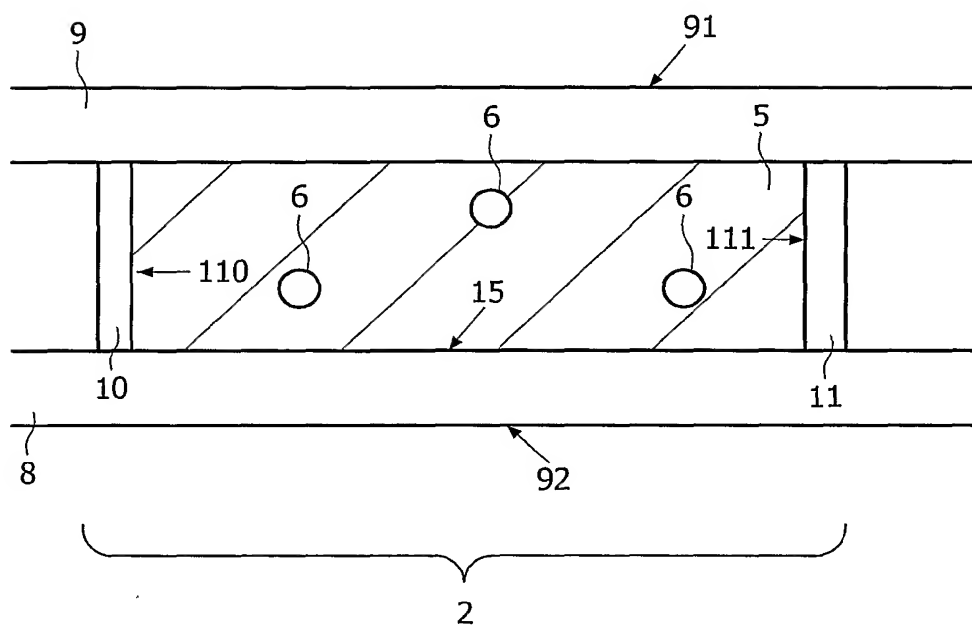


FIG. 2

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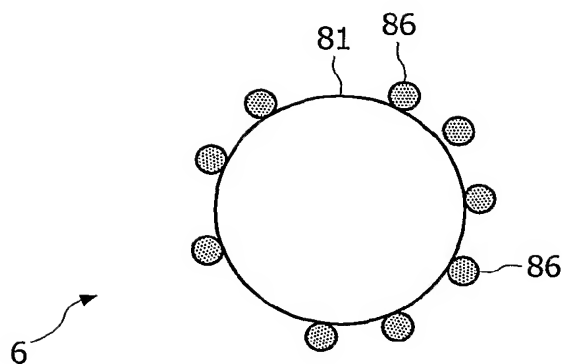


FIG. 3

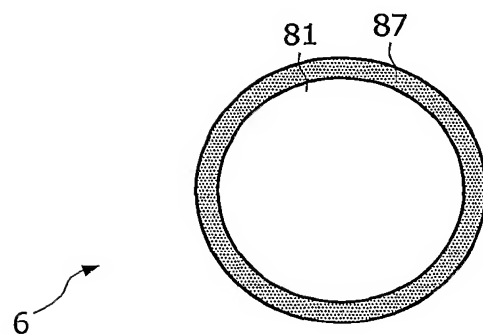


FIG. 4A

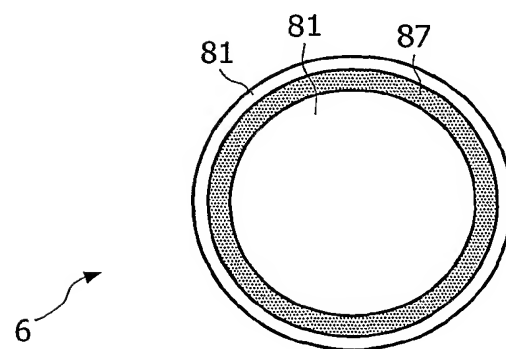


FIG. 4B

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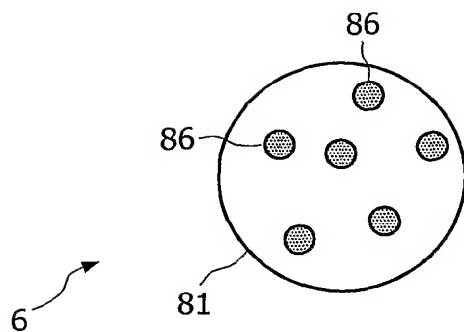


FIG. 5A

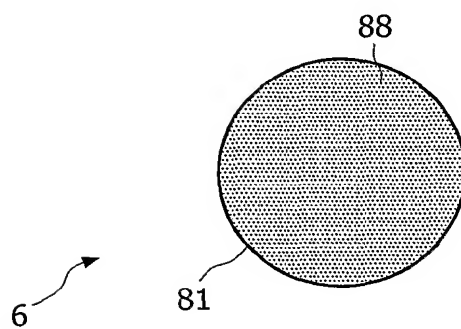


FIG. 5B

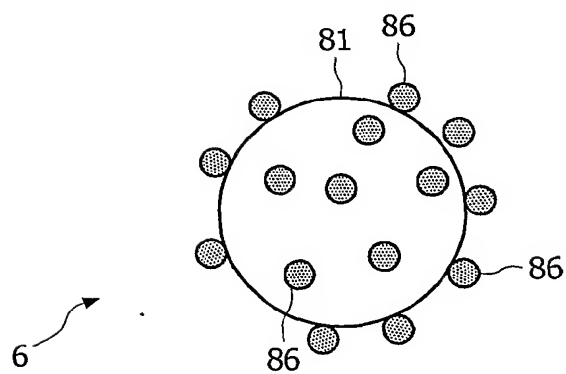


FIG. 6

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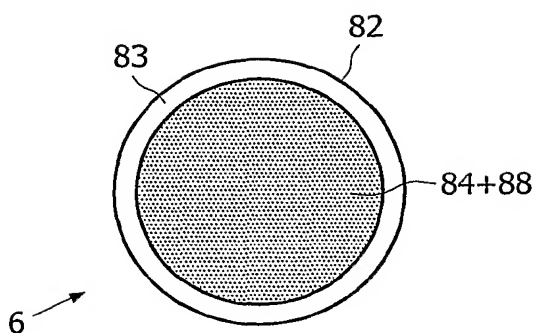


FIG. 7A

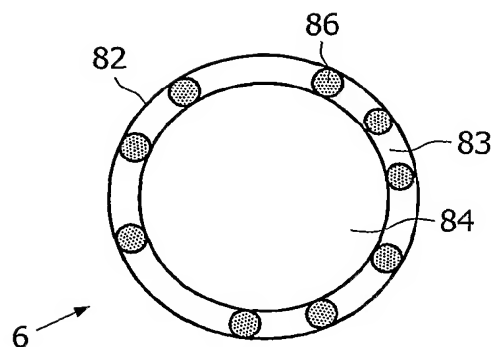


FIG. 7B

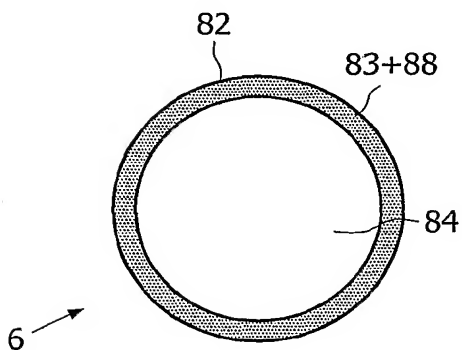


FIG. 7C

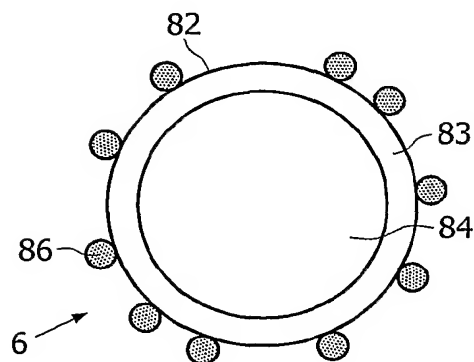


FIG. 7D

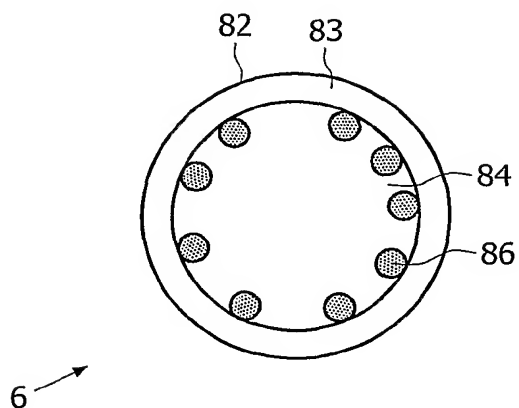


FIG. 7E

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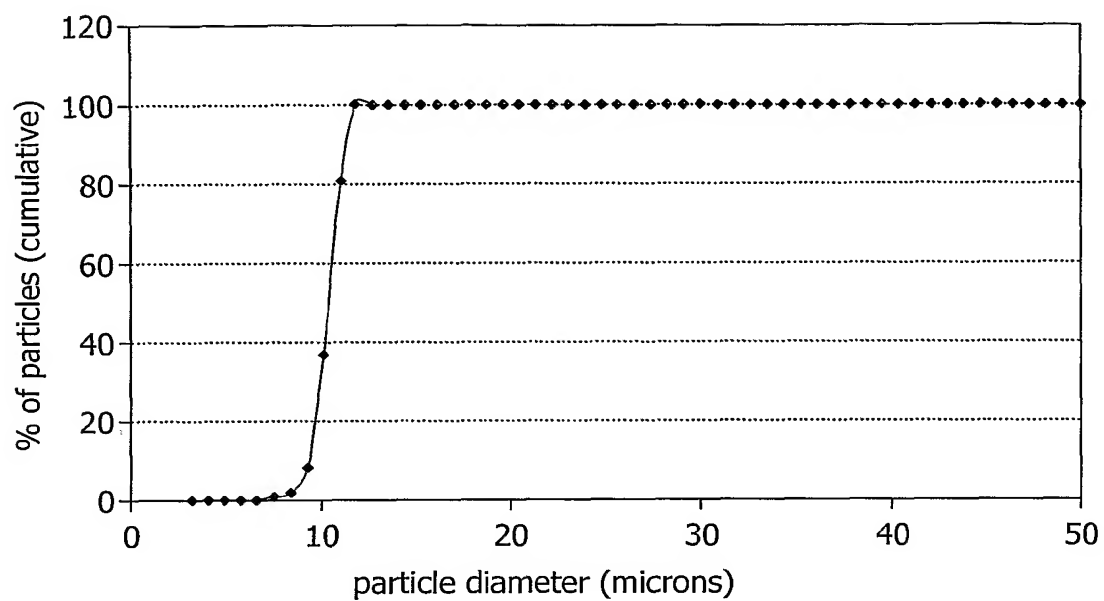


FIG. 8

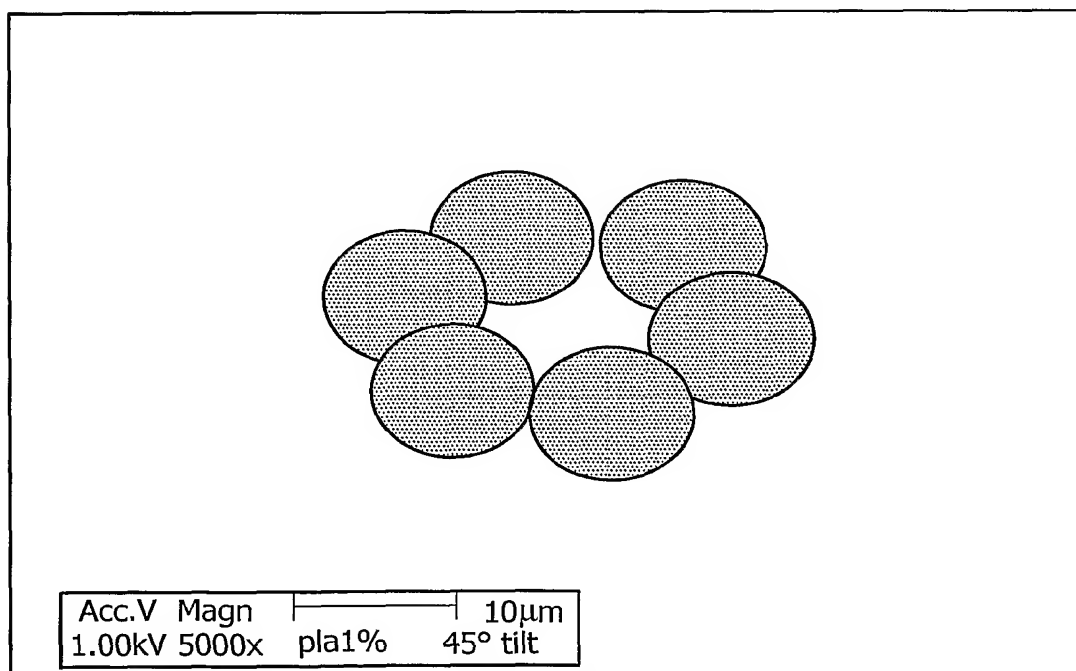


FIG. 9

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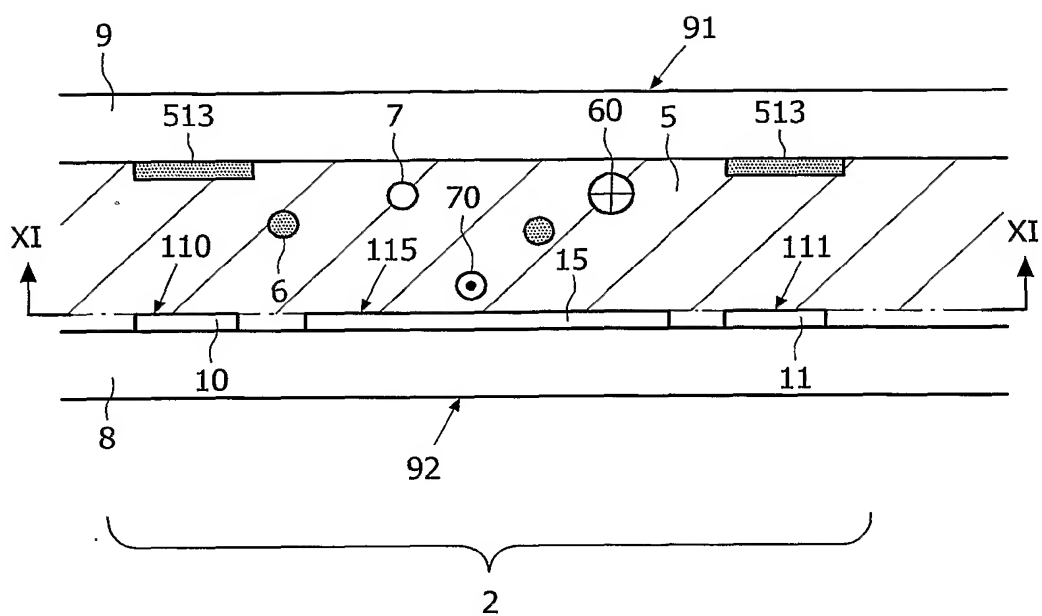


FIG. 10

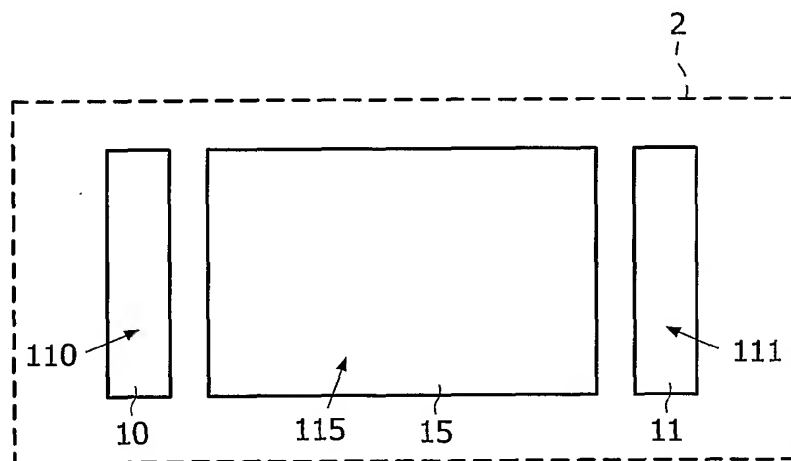


FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB2005/052223

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G02F1/167

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G02F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/227665 A1 (KAWAI HIDEYUKI) 11 December 2003 (2003-12-11) figures 2,3	1,2,5,6, 8-10, 12-14, 16,18-20
X	PATENT ABSTRACTS OF JAPAN vol. 2000, no. 11, 3 January 2001 (2001-01-03) -& JP 2000 227612 A (RICOH CO LTD), 15 August 2000 (2000-08-15) abstract	1,5,6,8, 13,18-20
P,X	WO 2004/074922 A (CANON KABUSHIKI KAISHA; TAKAGI, SHINYA) 2 September 2004 (2004-09-02) abstract; figures 5,6	1,2,5,6, 8,14,15, 18-20
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/052223

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 03/071348 A (KONINKLIJKE PHILIPS ELECTRONICS N.V.; SCHLANGEN, LUCAS, J., M) 28 August 2003 (2003-08-28) the whole document</p> <p>-----</p>	18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2005/052223

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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JP 2000227612	A	15-08-2000	NONE	
WO 2004074922	A	02-09-2004	NONE	
WO 03071348	A	28-08-2003	AU 2003202761 A1	09-09-2003
			CN 1633623 A	29-06-2005
			JP 2005517995 T	16-06-2005
			US 2005104843 A1	19-05-2005

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Basil, M. [US/US]; East Palo Alto, CA (US). **BLACK, John** [GB/US]; East Palo Alto, CA (US).

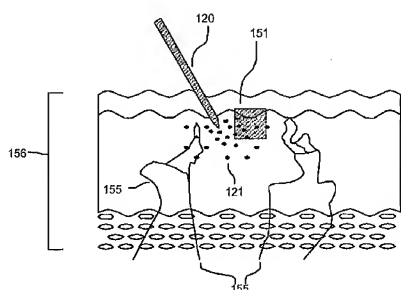
(74) Agents: **BANAIT, Narinder, S.** et al.; Fenwick & West LLP, Silicon Valley Center, 801 California Street, Mountain View, CA 94041 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

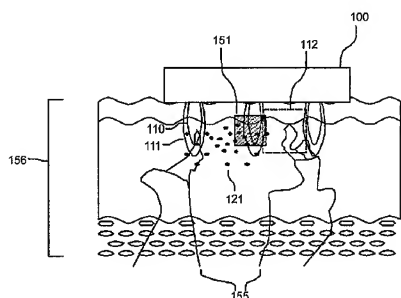
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[Continued on next page]

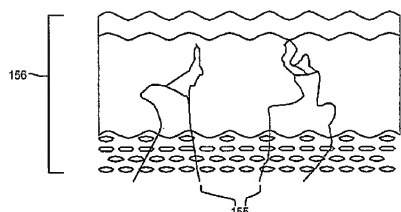
(54) Title: METHODS AND APPARATUS FOR MODULATION OF THE IMMUNE RESPONSE USING LIGHT-BASED FRACTIONAL TREATMENT



A



B



C

(57) Abstract: The invention describes a method and apparatus for the modulation of an immune response for the removal of a foreign body in skin or a visceral organ. A fractional phototherapy device is used to produce an acute stimulus for the immune response. The immune response may be enhanced by applying an exogenous substance. The immune modulation may be targeted or directed toward the treatment of a particular foreign body through the creation and amplification of particular biological signatures. This invention is particularly appropriate for treatment of skin cancer, autoimmune diseases, inflammatory diseases, and fungi.

WO 2006/036968 A2



FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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METHODS AND APPARATUS FOR MODULATION OF THE IMMUNE RESPONSE
USING LIGHT-BASED FRACTIONAL TREATMENT

INVENTORS

[0001] Nikolai I. Tankovich, Basil M. Hantash, and John Black

CROSS-REFERENCE TO RELATED APPLICATION

[0002] This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/613,303, "Photo-Fractional Immune Modulation Device and Method," filed September 28, 2004. The subject matter of the foregoing is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0003] This invention relates generally to medical laser and light emitting systems. More specifically, it relates to treating human skin or visceral organs using a fractional phototherapy device to modulate the human immune system through a biological signature and directed amplification with or without introduction of one or more selected exogenous agents.

BACKGROUND OF THE INVENTION

[0004] Medical laser treatments are commonly performed for vascular lesion removal, pigmented lesion removal, skin rejuvenation, tattoo removal, wrinkle reduction, etc. These common laser treatments are not directed towards the stimulation and direction of an immune response to attack a foreign body. For example, laser tattoo removal is accomplished by killing cells or groups of cells that contain or encapsulate tattoo ink particles. The tattoo particles are then flushed out of the skin by the lymphatic system in the absence of a concerted immune response directed to remove the tattoo ink particles.

[0005] Similarly, for laser treatment of dyschromia, melanocytes, keratinocytes, and melanophages are coagulated and the melanin is carried away as the coagulated cells are exfoliated or washed away by the lymphatic system. The removal of these cells occurs through a process that does not involve the immune system targeting the melanin or the melanin containing cells.

[0006] For laser skin rejuvenation, a laser can be used to stimulate a wound healing response by killing cells and coagulating tissue to stimulate collagen synthesis. The collagen remodeling is directed by fibroblast stimulation and subsequent collagen production does not involve the immune system.

[0007] There has been a reluctance to use lasers for treatment of cancer because there is a perceived risk of incomplete removal of the cancer cells, which may later metastasize and cause a fatal outcome. Standard treatments for cancers of the skin and visceral organs include cryotherapy and surgical removal. Both of these procedures are invasive, can leave scars, can discolor skin, and can leave behind residual cancer cells. Ineffective cancer treatments require follow-up procedures, such as chemotherapy and radiation therapy, that cause serious side effects such as liver, gastrointestinal, and bone marrow toxicity, with the latter leading to immune system suppression. This is in addition to the laundry list of less serious side effects such as hair loss and nausea. Neither surgery nor cryotherapy offers predictable cure rates, and metastasis is not uncommon despite follow-up with radiation or chemotherapy. To avoid ineffective treatment, physicians generally perform wider excisions and more aggressive adjunctive therapy in order to prevent the potentially life threatening outcome of metastasis. An effective cancer treatment that is less invasive is desired.

[0008] Non-fractional ablative lasers are not typically used for removal of foreign bodies such as cancer cells or tattoo ink particles that lie within the dermis because of the risk of excessive scarring. Nonablative lasers, such as Q-switched Nd:YAG lasers, can be used to remove some foreign bodies by breaking up the foreign body and reducing its size enough to allow the lymphatic system to carry it away in piecemeal. Nonablative lasers have not been used to remove a living foreign body such as a tumor because these lasers are not typically turned up to high enough fluence to cause necrosis of the cells. If these lasers are turned up high enough, then they cause the undesirable levels of scarring similar to the scarring caused by ablative lasers. The removal of foreign bodies through light-based stimulation of the immune system has not been described. It is desirable to use the immune system to assist in the removal of foreign bodies with higher efficacy, with less scarring, and/or with less invasiveness.

[0009] Fractional light-based treatment modalities have been described for treatment of wrinkles and other indications. Due to sparing of tissue around each treatment zone, fractional light-based treatments allow higher local fluence levels to be used without scarring than large area nonablative lasers. In addition to the general reluctance cited above for the use of light-based devices for cancer treatment, there has been a particular resistance to use fractional treatment due to the perceived partial tissue coverage of this type of treatment.

Apparatus and methods have not been designed to use the temporal and/or spatial signatures of fractional light-based treatment to enhance or suppress the immune system response.

[0010] Light-based treatments have been combined with exogenous agents to obtain a particular immune response. Apparatus and methods have not been designed to use the temporal and/or spatial signatures of light-based treatments in combination with exogenous agents to enhance or suppress the immune system response that is caused by the exogenous agent.

[0011] No one has directed the resensitization of a suppressed or blocked immune system using fractional light based treatments or using light based treatments in combination with pharmaceutical agents.

[0012] What is needed is a method and apparatus for stimulating the immune system to assist with the removal of foreign bodies and/or the treatment of cancer and inflammatory diseases in skin and visceral organs. Inflammatory diseases include but are not limited to infection and autoimmune diseases.

[0013] Several medical conditions result in lack of sensitivity by the immune system to a particular foreign presence in the body. The most important example is the presence of cancer, which can be fatal. Cancer cells frequently create an environment that promotes the growth of cancer cells while suppressing the activation of cytotoxic T-lymphocyte cells, which are a key part of the human immune response that would otherwise carry out the destruction of the cancer. The suppression of T-lymphocyte cells renders these cells unavailable in defeating the growth of new cancer cells leaving them to proliferate unchecked and eventually metastasize. Cancer remains one of the leading causes of death in the United States each year.

[0014] Cancer is typically treated with a multi-therapeutic approach incorporating the use of toxic systemic chemotherapy, radiation, surgical excision, and electrocautery. Frequently, these therapeutic regimens only transiently stabilize the rate of cancer growth while the cancers cells continue to mutate with each division, eventually rendering them resistant to the treatment modality. These therapeutic options also suffer from systemic side effects which inherently place the patient at risk of significant morbidity and possible mortality. For example, some of the side effects relate to immune suppression and involve a variety of systemic infections during the immunocompromised state. Therefore, a new

approach that stimulates the immune system to respond to a foreign body while avoiding systemic toxicity is needed.

[0015] Other light based treatment modalities are used to suppress the immune system. For example, ultraviolet light has been used to suppress the immune system in vitiligo, atopic dermatitis, psoriasis, and mycosis fungoides. Ultraviolet light has also been shown to suppress Langerhans cell function. There has been no evidence or suggestion that uniform illumination with ultraviolet light is sufficient to stimulate the immune system to fight cancer or dispose of foreign bodies. In fact, long-term ultraviolet light exposure has been linked to development of a variety of skin cancers as a result of creation of mutagens and chronic immune suppression. A device is needed that allows selective suppression and stimulation of the immune system with a reduced risk of forming mutagens.

[0016] There is indirect and direct evidence that laser-tissue interaction leads to partial immune stimulation with a variety of cytokines upregulated immediately after laser treatment of skin. However, light-based treatments have not been used to stimulate the immune system because they are broad area treatments. A limitation of broad area light-based treatments is that heating destroys some of the signal pathways necessary to orchestrate an appropriate immune response. Other light based treatments use low energies to avoid the destruction of the signal pathways, but these treatments do not create substantial stimulation of the immune system.

[0017] Anderson *et al.* (U.S. Patent Application #10/033,302) and Manstein *et al.* (PCT patent application PCT/US04/09452) disclose the use of light based therapies for the treatment of the skin and for the stimulation of wound healing response. However, these devices have not been targeted to stimulate the immune system selectively. The first phase of the wound healing response involves increasing vascularization to the injured site. However, this alone is inadequate to remove foreign bodies such as cancers. In fact, increasing angiogenesis may promote cancer growth. Promotion of wound healing alone is insufficient and a method to promote the immune system without turning on cancer promoting signals is needed.

[0018] Thus there is a need for methods and apparatuses to stimulate the immune system to attack foreign bodies present in the skin and the visceral organs of the patients. The present invention addresses the deficiency in the prior art and provides non-invasive and non-toxic methods and apparatuses for the modulation of immune responses. The inventive

methods and apparatuses thus overcome the problems of systemic chemotherapy which is fraught with systemic side effects.

SUMMARY OF THE INVENTION

[0019] The invention uses fractional phototherapy devices that provide acute stimulus thereby modulating the immune system. The invention provides methods whereby an immune response can be modulated by an acute stimulus provided by a fractional phototherapy device in order to achieve a desired treatment outcome. A fractional phototherapy device can be used in order to spare tissue between the injury zones that allows aspects of the immune response to be amplified and/or suppressed through interaction with vascular and cellular structures of the target tissue.

[0020] The fractional phototherapy device can emit treatment wavelengths in the range of about 180 nm to about 28000nm, such as, for example, 190-400 nm, 400-28000 nm, 1300-1900 nm, or 2000-2400 nm. The optical source of the treatment energy for the fractional phototherapy device may be a laser such as for example, a Nd:YAG, CO₂, holmium, Er:YAG, and/or Er:glass laser. The optical source can alternatively be a flash-lamp, a dye laser, a fiber laser, and/or a diode laser. The injury zones created by the fractional phototherapy device can have aspect ratios of depth:width of in the range of about 3:1 to about 10:1 and/or surface area:volume ratios in the range of about 20,000-100,000 m⁻¹.

[0021] Embodiments of the invention are directed to the treatment of inflammatory disease in visceral organs, inflammatory skin disease, noninflammatory skin disease, acne, psoriasis, alopecia areata, and/or vitiligo. In some cases, the stimulation of the immune system can be systemic.

[0022] In one embodiment of the invention, the immune system can be modulated and/or directed to attack one or more foreign bodies in a region of the skin or in a visceral organ, wherein the immune system removes a foreign body after immune cells are recruited and mobilized. In another embodiment, the foreign body is only partially removed or is changed in character. Examples of foreign bodies that can be attacked include skin cancer, tattoo ink particles, microbial infection, fungal infection, autoimmune disease cells, and/or human papilloma virus.

[0023] In another aspect of the invention, the treatment with a fractional phototherapy device can be performed in addition to surgical removal of at least part of a foreign body. At least part of the foreign body may be located within the dermis.

[0024] In another embodiment of the invention, an exogenous agent can optionally be used in conjunction with the stimulation by the fractional phototherapy device to direct or selectively modify the immune response. The exogenous agent can be introduced to the surface of the target tissue or may be introduced by the circulatory system. Examples of exogenous agents include stem cells, homing molecules, targeted stem cells, autologous immunotoxic cells, immunomodulators, vaccines, cytokines, growth factors, paracrine molecules, and/or chemotactic factors. Examples of autologous immunotoxic cells that can be used are natural killer cells and cytotoxic cells. Targeted stem cells are stem cells which are capable of being directed to a particular location in the body. Targeted stem cells can be created by genetically altering stem cells such that they express homing markers that bind to topographic specific markers thus enabling the stem cell to be directed to a particular location in the body.

[0025] In another embodiment of the invention, surface cooling is used to create a thermal inversion within the target tissue. Multiple passes may be made at an interval of 0.5 to 10 minutes. Multiple treatments can be used spaced at 1-2 week intervals.

[0026] In another aspect of the invention, only the periphery of a region containing a foreign body or presenting an undesirable condition can be treated.

[0027] Fractional treatment can create a homing signal for directing the immune system to a particular location. In this way, the dominant component of the immune response can be localized within 1 cm of the area treated by the fractional phototherapy device.

In one aspect of the invention, method is provided for modulating the immune response of a subject. The method can comprise contacting a fractional phototherapy device with a target tissue wherein the immune response is modulated, and wherein the target tissue is skin or a visceral organ. The fractional phototherapy device can emit energy with a wavelength of about 400 nm to about 28,000 nm, of about 190 nm to about 400 nm, of about 1300 nm to about 1900 nm, or of about 2000 nm to about 2400 nm. The fractional phototherapy device can be a erbium-doped fiber laser.

[0028]

[0029] Other aspects of the invention include apparatuses corresponding to the methods described above. These and other aspects of the present invention will become evident upon reference to the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] The invention has other advantages and features which will be more readily apparent from the following detailed description of the invention and the appended claims, when taken in conjunction with the accompanying drawings, in which:

[0031] FIGURE 1 depicts the modulation of the immune response using a fractional phototherapy device for the removal of a foreign body within the skin or a visceral organ. In FIGURE 1A, the optional exogenous agent (121) is introduced near the foreign body (151). In FIGURE 1B, a fractional phototherapy device (100) is applied creating the injury zones (110) and the untreated tissue (112), and to modulate the immune response. In FIGURE 1C, the foreign body is removed by the treatment.

[0032] FIGURE 2 is a graph that shows the variation of the dimensions of the injury zones for a particular fractional phototherapy device that can be used in some aspects of this invention.

[0033] FIGURE 3 shows the acute cellular-derived inflammatory response that can be created in response to application of a fractional phototherapy device.

DETAILED DESCRIPTION

Definitions

[0034] Immune cells are cells that help protect the body against anything perceived as foreign by the host. Examples of immune cells include T lymphocytes, B lymphocytes, macrophages, and natural killer cells (NK cells).

[0035] An injury zone is a contiguous region of tissue that is coagulated by a fractional phototherapy device.

[0036] An inflammation zone is a region around an injury zone in which an inflammatory response is triggered by treatment with a fractional phototherapy device. The size or character of the inflammation zone may be affected by the treatment energy delivered by the fractional phototherapy device or by the presence or absence of an exogenous agent. The inflammation zone does not comprise the injury zone.

[0037] "Untreated tissue" refers to tissue not part of the injury zone.

[0038] Exogenous agents are agents that come from outside the body. Exogenous agents include agents that are derived from the body and later reintroduced into the body, such as autologous stem cells, for example.

[0039] As used herein, the terms “treat” or “treatment” are used interchangeably and are meant to indicate a postponement of development of diseases and/or a reduction in the severity of such symptoms that will or are expected to develop. The terms further include ameliorating existing symptoms, preventing additional symptoms, and ameliorating or preventing the underlying metabolic causes of symptoms.

[0040] The term “optional” or “optionally” means that the subsequently described event or circumstance may or may not occur, and that the description includes instances where the event or circumstance occurs and instances where it does not. For example, the phrase “optionally another drug” means that the patient may or may not be given a drug in conjunction with the fractional phototherapy described herein.

[0041] The term “modulating” refers the inhibition or promotion of the activity of the immune response or concentration of any enzyme or regulatory molecule involved in the immune response in a cell or animal. Modulator can be a fractional phototherapy device, a polypeptide, nucleic acid, macromolecule, complex, molecule, small molecule, compound, or the like (naturally occurring or non-naturally occurring) that is capable of causing modulation.

Description

[0042] In some diseases of the skin or visceral organs, the unassisted immune response has failed to respond adequately. Therefore, treatment can be affected by appropriately stimulating the target region in order to reprogram the immune system to once again recognize foreign bodies that cause the skin disease. Examples of such foreign bodies include malignant cells, viruses, fungi, microbes, or autoimmune cells and antibodies, amongst others. The treatment of each of these foreign bodies can be performed through combining a fractional phototherapy device with topical immunomodulators and/or vaccines. In other situations, the immune system can be hypersensitive and the immune response can be beneficially suppressed or modified. For example, in inflammatory skin diseases, the inflammatory response typically exceeds desirable levels. The excess inflammatory response can be counterbalanced with the appropriate immunostimulation, for example by blocking undesirable signaling pathways.

[0043] The present invention discloses methods and apparatuses for modulating the immune system response to trigger the immune system to attack one or more undesirable foreign bodies within the tissue. In one aspect of the invention, the immune response can be modulated by applying energy. The energy can be light, heat, or mechanical energy, such as,

for example, energy provided by UV, visible, infra red or near infrared sources, contact heat, or RF heat, or mechanical energy provided by tapping, messaging, mechanical stimulation, and the like. A preferred embodiment of the invention comprises the use of a fractional phototherapy device to stimulate or suppress the immune system with the optional addition of an exogenous agent that enhances and/or directs a response of the immune system.

[0044] One embodiment of the invention is illustrated in FIGURE 1. In FIGURE 1A, a needle 120 is inserted into the tissue 156 to inject an exogenous agent 121. Depending on the location of the foreign body 151 that is to be removed and the types of immune cells that will be stimulated, the optional exogenous agent 121 may be injected into a selected layer within the tissue 156. After the exogenous agent 121 has been injected into the tissue 156, the fractional phototherapy device 100 can be used to illuminate the skin to create discrete injury zones 110 as shown in FIGURE 1B. Injury zones may reach the surface or may be located entirely below the surface, for example, within the dermis of the skin. Without being bound to theory, the cells within the injury zones 110 are coagulated by the light treatment and some of these cells release cytokines in response to the optical treatment. The released cytokines migrate to the blood vessels 155 and stimulate an immune response that attacks and removes a foreign body 151 as shown in FIGURE 1C. Between at least some of the injury zones 110 are inflammation zones 111 wherein the immune system is stimulated by the treatment with the fractional phototherapy device 100 but the tissue 156 is not coagulated. There will be untreated tissue regions 112 between the injury zones 110 wherein the tissue is not coagulated. The untreated tissue regions 112 can include inflammation zones 111.

[0045] In one aspect of the invention, the fractional phototherapy device 100 is a FRAXELTM SR laser system (Reliant Technologies, Inc. Palo Alto, CA). The FRAXELTM SR laser system incorporates an erbium doped fiber laser that operates at a wavelength of 1550 nm and uses a microscopic beam that is nearly collimated as it enters the skin. An example of a fractional phototherapy device 100 is described in co-pending U.S. Applications No. 10/367,582, entitled "Method and apparatus for treating skin using patterns of optical energy" and No. 10/888,356, entitled "Method and Apparatus for fractional photo therapy of skin" which are incorporated herein by reference.

[0046] The use of optical energy is preferred over contact heating or RF energy because optical energy can be better controlled to deliver smaller spot sizes than other energy types. This is beneficial for creation of many patterns of stimulation for the immune response.

[0047] In one aspect of the invention, the fractional phototherapy device has a wavelength in the range of about 180 nm to about 30,000 nm, preferably about 400-28,000 nm. The wavelengths in this range can be produced using a flash-lamp, a free electron laser, and/or an optical parametric oscillator pumped by a laser. Other types of laser sources can be used to create light at selected wavelengths within the range of 400-28,000 nm. For example CO₂, erbium-doped fiber, Er:YAG, Er:glass, holmium, dye, thulium-doped fiber, diode, Nd:YAG, and Nd:YAP lasers can be used. Tunable lasers can also be used to allow additional flexibility for treatment. Frequency doubling can also be used, for example, with a Nd:YAG laser.

[0048] The fractional phototherapy device can produce injury zones 110 with small diameters or large diameters have an aspect ratio of depth to width of greater than 2:1 or in the range of about 3:1 to about 10:1 are desired. In other embodiments, certain immune responses can be created by using injury zones with a large ratio of surface area to volume such as in the range of about 20,000-100,000 m⁻¹. Larger surface area to volume ratios can advantageously allow a larger percentage of immunomodulators to diffuse from the injury zone to the adjacent viable tissue. To create injury zones 110 with large aspect ratios, large surface area to volume ratios, and/or small diameters, wavelengths that have low scattering and low absorption within the skin are preferred. Such wavelengths occur in the wavelength range from about 1300-1900 nm and in the range of about 2000-2400 nm. Ultraviolet wavelengths such as 190-400 nm are particularly useful for immune suppression in the upper layers of the tissue. The choice of optical source (e.g. laser) and optical wavelength for the fractional phototherapy device can be made by determining the desired depth, width, shape, and location of the injury zones and then using Monte Carlo simulations to model the absorption, scattering, and thermal diffusion within the tissue 156.

[0049] Returning to FIGURE 1, FIGURE 1A shows an exogenous agent 121 in contact with tissue 156. The exogenous agent 121 can be delivered by one or more known methods, such as injected directly to the site using a needle 120, by transdermal delivery, or via systemic delivery using oral, intravenous, or intramuscular delivery. The exogenous agent 121 can also be delivered via topical routes, for example, by application to the surface of tissue 156. As one of skill in the art will recognize, combination methods can be used to deliver one or more exogenous agents 121 to the target region.

[0050] The exogenous agent 121 can be, for example, a pharmaceutical agent, a nutraceutical, a drug, a vitamin, an immunomodulator, stem cells, autologous immunotoxic cells, an exogenous immune or other type of cell, or an agent that contains one or more active ingredients that promote immune modulation, or combinations thereof. In some situations, the exogenous agents may be naturally present at levels that are not sufficient to cause therapeutic benefits at the desired level. For example, cellular-derived growth factors may be naturally occurring within the skin, but the concentration of cellular-derived growth factor may provide insufficient stimulation of the immune response to cause the desired treatment.

[0051] An advantage of the use of fractional phototherapy device 100 with an exogenous agent 120 delivered by the circulatory system in comparison to the use of the exogenous agent 120 alone is that the treatment with the fractional phototherapy device 100 can direct the immune response to a selected location. For an exogenous agent 120 that has been delivered into the circulatory system, an immune response will be induced in the circulatory system. In the absence of a homing signal, the immune response becomes diluted by traveling throughout the body in a non-selective fashion. This renders the immune response ineffective. Treatment with the fractional phototherapy device 100 can provide a homing signal that triggers the immune response to address the target region.

[0052] The invention provides methods and apparatuses for the treatment of a subject having a foreign body 151 located in or on the tissue 156. The tissue 156 is preferably skin, and the subject is preferably human. The method and apparatus of the invention may also be directed towards a foreign body 151 located in tissue 156 of a visceral organ, such as for example, the lungs, heart, liver, kidney, and bladder.

[0053] Foreign body 151 may comprise, for example, a cluster of skin cancer cells, tattoo ink particles, pathological inflammatory cells, antigens, and/or infectious agents. Following treatment, the foreign body 151 may be removed fully as depicted in FIGURE 1C, may be removed partially, or may be changed only in character by a targeted immune response.

[0054] By modulating the immune system through a stimulus created using a fractional phototherapy device 100, a concert of signals will be generated that otherwise would be destroyed or weakened by non-fractional treatment. In one aspect of the invention, a specific biological signature of thermal injury can be created which leads to a very specific response by the immune system. The induced signal can promote immune resensitization locally at the

site of injury. The subsequent resensitization can allow the body to reactivate its fight against cancers such as melanoma, basal cell carcinoma, and squamous cell carcinoma, amongst others. Without immune resensitization, the body is unable to recognize the cancer and no immune response is mounted against the harmful cancer cells.

[0055] FIGURE 1 shows that the exogenous agent 121 is introduced prior to the treatment by the fractional phototherapy device 100. In alternate embodiments, the substance may be introduced during or after the optical treatment with the fractional phototherapy device 100. To achieve synergistic effects on the immune response, a preferred embodiment comprises treatment with the fractional phototherapy device 100 that occurs within 3 or within 12 hours of delivery of the exogenous agent 121 to the target region.

[0056] The immune system response can be directed by controllably modulating the balance between cytotoxic CD8 T-lymphocytes and helper CD4 T-lymphocytes. The fractional phototherapy device 100 can be used to stimulate the immune system by increasing the concentration of CD4 cells relative to the concentration of CD8 cells within the target region of tissue 156. Illumination from the fractional phototherapy device 100 can stimulate T-lymphocytes that are CD4+ CD8- in nature. These cells are known as T-helper cells. This immune response promotes the recruitment of eosinophils and other immune cells. Interaction of the T-helper cells with B-lymphocytes stimulates the production of antibodies that attack particular antigens recognized as foreign by the immune system. The antibodies can thus be created to attack a foreign body 151, such as for example cells expressing melanoma, viral, fungal, or bacterial antigens.

[0057] In an alternate embodiment, the immune response can stimulate the production of CD4- CD8+ T-lymphocytes which are cytotoxic in nature. These cells are able to effect cellular destruction of antigens perceived as foreign. Cytotoxic stimulation can be used to reintroduce or amplify immune sensitivity in cases where the body does not have adequate sensitivity to a particular foreign body 151 such as for example a cluster of cancer cells or a tattoo.

[0058] Each immune response has a particular function and can be regulated. There are times where both CD4+ CD8- and CD4- CD8+ responses can be advantageously increased or decreased. The coordinated regulation of these two types of immune response is not typical since each immune response releases immune mediators that act to inhibit the other arm of the immune system. For example, CD4+ CD8- T-cells are able to generate immune signals

such as IL-10 which act to shut down the cytotoxic T-cell response. Similarly, CD4- CD8+ T-cells are able to shut down T-helper cell response through release of a different panel of cytokines. Thus, within each positive stimulatory response, there exists a coordinated suppression of the other arm in most cases. A fractional phototherapy device 100 can be used with or without an optional exogenous agent 121 to create a coordinated regulation of the CD4+ CD8- and CD4- CD8+ types of immune response. By using the spatial signature from a treatment with a fractional phototherapy device to direct the immune response, a particular region of treatment can lead to stimulation of CD4+ CD8- predominant responses in one portion and CD4- CD8+ predominant responses in an adjacent but distinct zone of the same treatment region. Thus, the fractional phototherapy device allows intricate spatial control and direction of the immune response.

[0059] In an alternate embodiment, other specialized immune cells may also be selectively activated or suppressed. Examples of these immune cells are natural killer cells, macrophages, monocytes, neutrophils, eosinophils, basophils, mast cells, histiocytes, dendritic cells, and langerhans cells.

[0060] Non-fractional phototherapy devices are limited in their ability to predictably achieve particular immune responses. A treatment of a skin cancer that extends from the surface of the tissue 156 to beyond the junction between the epidermis and dermis can be approached using two methods that use a non-fractional phototherapy device: A first method is to kill the cancer cells by heating the cells until they are dead or physically ablated from the skin. This process can be effective but has a high incidence of scarring and can be invasive. A second method is to heat the cells or surrounding cells to sufficient temperature to stimulate an immune response that may remove the cancer cells. With a non-fractional phototherapy device, the intensity of the stimulation that is preferred to provide predictable treatment increases the tissue temperature above 42°C. This thermal condition denatures many large proteins, such as growth factors, cytokines, and paracrine hormones that would otherwise act as immunostimulators. Therefore, when performing treatment with a non-fractional phototherapy device, a large percentage of the proteins within the treatment region can be denatured. The denaturation of a large percentage of particular immunostimulators by a non-fractional phototherapy device blunts much of the expected immune response due to denaturation of the critical immunostimulator molecules necessary to initiate and amplify the immune response cascade.

[0061] In another aspect of the invention, methods are provided for using a fractional phototherapy device 100 to stimulate an acute immune response that can be amplified in the inflammation zones 111 and/or in the untreated tissue regions 112 around and/or between the injury zones 110. In some cases of fractional treatment, the inflammation zones 111 from adjacent injury zones 110 can merge together. Fractional treatment can be used to create an acute response as with non-fractional treatment, but the microscopic size of the injury zone 110 allows a higher percentage of active immunostimulators to be available in the inflammation zones 111 and/or in the untreated tissue regions 112 where they can participate in and/or initiate the immune response cascade.

[0062] The method of the invention provide for uncoagulated tissue being present in between the injury zones. The presence of uncoagulated tissue in the regions between injury zones 110 preserves native structure of the immune mediator signals that can be released from cells in the target region during the amplification process. Without being bound to theory, the uncoagulated tissue can amplify the immune signal and allow the immune signal to propagate. Amplification and propagation can provide positive feedback for the initial immunostimulation performed by the fractional phototherapy device 100 and thus cause more vigorous host response and improve the likelihood of immune resensitization and subsequent removal a foreign body 151.

[0063] Fractional treatment allows higher treatment levels without scarring than would be possible with non-fractional treatment. This can be used to selectively increase the circulation of preexisting immunosurveillance cells.

[0064] The percentage of active immunostimulators can be affected significantly by the size of the injury zones 110 and the separation between adjacent injury zones 110. Injury zones 110 with diameters of 50-500 μ m or 50-200 μ m are preferred in order to allow a significant fraction of the immunostimulators to diffuse out of the injury zones 110. Injury zones 110 will preferably penetrate into the dermis 153 so that the immunostimulators released by the fractional phototherapy device 100 will be able to quickly diffuse to the blood vessels 155 to recruit the desired immune cells to the treatment site.

[0065] FIGS 2A and 2B show the average dimensions for injury zones 110 created by the FRAXELTM SR laser system for *in vivo* and *ex vivo* human skin. The average dimensions for injury zones 110 created by the FRAXELTM SR laser system can vary in width in the

range of approximately 50-200 μm and depth in the range of approximately 350-900 μm . Injury zones 110 of other dimensions can be created using other optical configurations.

[0066] Using a fractional pattern of delivery allows each biological signature to be controlled temporally and spatially, thus permitting a unique form of dosimetry. Immunostimulation can therefore be tailored to each foreign body 151. Specific immune responses can be generated by appropriately choosing the parameters of the fractional phototherapy device 100. These parameters can include pulse energy, separation between injury zones 110, density of injury zones 110, cooling of the surface of tissue 156, and diameter, depth, shape, and aspect ratio of each injury zone 110. In a preferred embodiment, treatment parameters can be chosen to generate a wide array of biological signatures that mimic the biological signatures of immune responses to different types of pathological conditions. A biological signature is a specific set of immune mediators at specific concentrations. The ability to create a selected biological signature during thermal injury of skin is made possible by the presence of uncoagulated tissue between the injury zones 110. In the absence of tissue sparing at the microscopic level, much of the response would be abolished or blunted. The fractional phototherapy device 100 can create biological signatures that are not part of the wide array created by the human body. This feature provides a novel mechanism to selectively activate unique non-physiological signatures advantageous to effecting removal of foreign bodies.

[0067] The immune mediators which constitute the biological signature include cytokines such as TNF-alpha, IFN-gamma, IL-1, IL-2, IL-4, IL-5, , IL-8, IL-10, IL-12; growth factors such as TGF-beta1, TGF-beta3, VEGF, PDGF, KGF, FGF, stem cell growth factor; paracrine molecules such as histamine, bradykinin, substance P; and chemotactic factors such as C5a, ECP, and LTB4. Each particular set of treatment parameters will generate a biological signature. The biological signature can be tailored to the foreign body 151 present. This allows the user to resensitize the immune system to a foreign body 151. The treatment with a fractional phototherapy device 100 may be combined with an exogenous agent 121 such as for example efudex or imiquimod to further increase the intensity of the host response.

[0068] The biological signature can be enhanced by providing one or more subsequent treatments with the fractional phototherapy device 100, with an exogenous agent 121, or with a combination of the two. The subsequent treatments can create a second set of injury zones

and stimulate the release of a second set of cytokines that can enhance an immune response through amplification.

[0069] The biological signature can also be enhanced by optionally applying non-fractional variations of thermal profiles within the layers of the tissue 156. For example, a mild uniform heating of 5-10°C applied at the surface of tissue 156 can be used to provide additional stimulation of selected immune responses. There can also be a temporal thermal signature that is used to heat or cool the tissue as the immune system reacts in order to better facilitate healing. Cycles of heating and cooling may also be used to enhance the immune modulation. In some tissue conditions, CD4+ and CD8+ cells may thrive at different temperatures. In these cases, the balance between CD4+ and CD8+ cells can be controlled by varying a controlled temperature profile following treatment with a fractional phototherapy device 100. The controlled temperature profile can be fractional or non-fractional and can vary with depth into the tissue as a function of time.

[0070] An immune response can be induced within the tissue itself by activating preexisting resident immune cells such as Langerhans cells, dendritic cells, macrophages, histiocytes, and mast cells. For example, FIGS 3A, 3B, 3C, and 3D show the response of Langerhans cells 160, epithelial cells 162, macrophages 164, and fibroblasts 166, respectively. The responses illustrated in FIGS 3A-3D are shown separately for clarity. In practice, multiple responses can be stimulated simultaneously by the acute injury zone created by a fractional phototherapy device.

[0071] FIGURE 3A shows Langerhans cells 160 within the epidermis 152 of skin 150. Some of these Langerhans cells 160 are affected by the fractional phototherapy device 100, while others are not affected. The affected Langerhans cells 160 can release, for example, cytokines 161. FIGS 3B, 3C, and 3D show the response of epithelial cells 162, macrophages 164, and fibroblasts 164 within the epidermis 152 and/or dermis 153. In each of these cases, cells are coagulated by a treatment with a fractional photothermal device 100 release cellular derived growth factors 163 that can stimulate or suppress an immune response.

[0072] The response of the Langerhans cells 160, epithelial cells 162, macrophages 164, and/or fibroblasts 164 can be amplified or suppressed in the presence of an exogenous agent 121.

[0073] In one embodiment, the foreign body 151 can be a cluster of cancer cells. A fractional phototherapy device 100 can treat a target region that comprises the cancer cells to

produce a stimulus that is co-localized within the target region and thus provides a homing signal for directing the immune response. By thus co-localizing the immune system response to the site of cancer, the host immune response can attack and destroy the skin cancer. The immune response can thus be predominantly located within 1 cm of the treatment to provide a targeted response of the immune system.

[0074] In another preferred embodiment, the foreign body 151 is a cluster of skin cancer cells. The fractional device 100 can be used to treat the target area subsequent to a first treatment course of cryotherapy, surgery, and/or laser surgery. The fractional phototherapy device 100 can be used to stimulate an immune response to attack any cancer cells that are not removed by the first treatment course. The use of the fractional phototherapy device 100 after the first treatment course has the benefit of providing additional therapy that reduces the chance of not treating or removing all of the cancer cells of the cluster of skin cancer cells and thus reduces the incidence of residual cancer cells metastasizing. The treatment provided by the fractional phototherapy device 100 can be noninvasive and may supplement a more invasive first treatment course to allow the first treatment course to be made less invasive. Bulk laser treatment can be used in certain cases where a general immune system response is desired. In many cases, fractional treatment is preferred over non-fractional treatment because fractional treatment can provide a better tolerated acute immune stimulus and allows the immune response to be amplified by the tissue outside each injury zone.

[0075] Basal cell carcinoma is the most common cancer in both sexes. Only relatively superficial basal cell carcinomas can be treated topically. For example, 5-fluorouracil or imiquimod can be applied topically or injected. A limitation of topical application is that these medications are unable to reach deeper tissues and thus are not considered reliable for removal of basal cell carcinomas that penetrate deeper than the dermal-epidermal junction. A fractional phototherapy device can be used to provide an acute immune stimulus that can be combined with topical therapies to produce an immune response that is effective for removing skin cancers that extend deeper into the tissue 156 than could be addressed by topicals alone. Since only a fraction of the skin is treated, the incidence of side effects is reduced.

[0076] The combination treatment can be further enhanced by creating an inverted thermal profile in which the temperature of deeper tissue is increased, while the temperature of shallow tissue is increased by a smaller amount or reduced in temperature by using surface cooling. The inverted thermal profile can provide significant immune system stimulation

deeper within the tissue where topical penetration is typically low. The immunostimulation can be varied by adjusting optical pulse fluence, optical pulse duration, optical power, pulse interval, and/or separation between treatment zones. In one aspect of the invention, the temperature profile within the skin can be adjusted through the adjustment of the timing, amount, and location of tissue cooling and heating. The tissue may, for example, be cooled with a cryogenic spray or heated with a resistive heater that is placed in thermal contact with the tissue 156. Thus, the immune stimulation provided by treatment with the fractional photothermal device 100 can be adjusted to achieve a biological signature that is appropriate for removal of the foreign body based on the location and characteristics of the foreign body.

[0077] Unlike basal cell carcinoma, malignant melanoma is very rapidly growing skin cancer that frequently can metastasize, leading to fatal outcomes. Malignant melanoma is therefore treated more aggressively. Malignant melanoma is often found in the epidermis 152 (FIGURE 3). Malignant melanoma cells may be found in discontinuous patches, unlike basal cell carcinoma which grows in monolithic clusters or nodules in the skin. Multiple passes and/or treatments can be used to amplify the immune response. Each additional pass and/or treatment can be administered after the tissue has already cooled and the immune mediators have been released. In the preferred embodiment, multiple passes are spaced at 0.5 to 10 minute intervals. The interval allows the immune mediators time to reach the target area, but does not allow enough time for them to dissipate significantly. The viable tissue in the regions between injury zones 110 comprise regions where amplification can occur through the further release of immune stimulators. The amplification of the immune response through multiple passes and/or treatments increases the chance of successful cure of aggressive and potentially fatal cancers, such as for example malignant melanoma, at a stage prior to metastasis.

[0078] Malignant melanoma treatment by surgical excision doesn't address the problem of potential future recurrence. The present invention provides methods for reducing the likelihood of recurrence of malignant melanoma by treatment with a fractional phototherapy device 100. For example, a vaccine containing melanoma antigens can be injected into the skin or muscle during the same office visit as treatment is performed with a fractional phototherapy device 100. During the initial treatment, the immune system can be focused at the site of melanoma by creating a homing signal by treatment with the fractional phototherapy device 100. This allows for a boosted immune response to the vaccine.

Subsequent treatments of the melanoma site with the fractional phototherapy device 100 can be made with or without additional vaccine at 1 to 2 week intervals, or at an interval where the vaccine response curve is near its peak and can be amplified by treatment with the fractional phototherapy device 100 at times near the peak of the immune response. Repeated injury over time can be used to recruit the vaccine-derived immune response to the site of cancer. Thus, a fractional phototherapy device 100 can also serve as a homing device or signal for the host response.

[0079] Another potential therapeutic use for the invention is for the treatment of autoimmune disorders that affect the skin and/or visceral organs. For example, alopecia areata represents a condition whereby immune cells of a patient attack and destroy hair follicles. The available immunosuppressive therapies to treat this condition frequently are ineffective, and, in addition, result in significant incidences of systemic side effects. In one embodiment of the invention, the methods and apparatuses disclosed in detail above can be used for the treatment of alopecia areata. The inventive methods are advantageous since a lower incidence of systemic side effects occur. A biological signature effective for the treatment of alopecia areata can be selected. The biological signature can be tailored to counter the characteristic immune response that is responsible for destroying the hair follicle in alopecia areata. Alopecia areata animal models have shown that transfer of CD8⁺ T-lymphocytes to hair-bearing mice can lead to localized hair loss. On the other hand, transfer of CD4⁺/CD25⁺ T-lymphocytes led to a hair loss blockade. Thus, the treatment parameters for the fractional phototherapy device can be selected for example to recruit a predominance of CD4⁺/CD25⁺ T-lymphocytes while blocking the recruitment of destructive CD8⁺ T-lymphocytes.

[0080] The process of selection of a particular biological signature is a powerful tool for the treatment of autoimmune diseases. Other examples of autoimmune diseases that can be treated using the methods and apparatuses of the invention include lupus erythematosus, vitiligo, and rheumatoid arthritis. Thus, in one aspect of the invention, the fractional phototherapy treatment around the periphery of a patch of vitiligo can be used to stimulate an immune response that blocks the autoimmune destruction of melanocytes allowing for repigmentation of the treated area. More than one treatment may be required to suspend the autoimmune response against melanocytes.

[0081] In another aspect of the invention, immune system overactivity can be locally modulated for the treatment of inflammatory diseases. Inflammatory skin diseases such as for example psoriasis, atopic dermatitis, and acne can be treated by modulating the arm of the immune system which is aberrantly overactive. Inflammatory diseases can also result from immune hyperactivity in visceral organs. For example, inflammatory bowel disease results from immune hyperactivity and can be treated using this invention.

[0082] In atopic dermatitis, CD4+ response is overactive, and this leads to the release of ECP and IL-4 and IL-5, which helps increase the concentration of eosinophils. Although eosinophils are useful in the fight against various parasitic infections, these cells often are increased in conditions that involve allergy. Creating a biological signature that selectively increases the CD8+ immune profile can be used to dampen the allergic host response. The methods and apparatuses of the invention can be used for the treatment of atopic dermatitis wherein thermal injury zones capable of achieving such a signature can be created. Similar parameters can be used to treat other inflammatory conditions that require immune suppression of CD4+ overactivity.

[0083] In another example of a condition that can be treated by stimulating, resensitizing, or modulating the immune system using a fractional phototherapy device 100 is human papilloma virus (HPV) infection, commonly known as warts. This condition can be difficult to treat medically, especially in acral locations such as the palms and soles, because typical topical therapies alone do not cause a sufficiently vigorous immune response that is specific to the particular HPV strain. By choosing appropriate treatment parameters for the fractional phototherapy device 100, the physician can create a biological signature that is specific to activating cytotoxic T-lymphocytes required for the destruction of viruses, such as for example HPV. Treatment with a fractional phototherapy device 100 can optionally be enhanced by topical application of an agent, such as, imiquimod, cryotherapy, efudex, bleomycin, salicylic acid, and the like.

[0084] In another aspect of the invention, methods and apparatuses disclosed herein can be used to modulate the immune response for the treatment of fungal infection. Fungal infections can be treated by choosing treatment parameters to create a biological signature that activates an immune response specific to destruction of fungal organisms. The biological signature can, for example, create biological signatures that activate T-helper cell populations and increase recruitment of eosinophils by eosinophil cationic proteins. Eosinophils can then

destroy the fungi that have invaded a tissue. For example, fungal infections of the toenail can be treated using the fractional phototherapy device 100 applied around the nail bed or periungual skin at the periphery of the infected nail.

[0085] In yet another aspect of the invention, methods and apparatuses disclosed herein can be used to modulate the immune response for the removal of tattoos, and other biologically inert foreign bodies. Some foreign bodies are not recognized by the immune system and therefore are biologically inert. Examples of biologically inert foreign bodies include tattoo inks and encapsulation materials used for encapsulating tattoo inks. Tattoo inks have been treated with nanosecond pulse lasers that rely on absorption of the laser energy by the ink leading to its fractionation into smaller particles. Not all colors of tattoo inks have sufficient absorption at selected laser wavelengths and this has meant that physicians do not get the desired response or must repeat treatment many times to get adequate results. The patient can thus be subjected to significant pain and a higher risk of scarring. Since the immune system is capable of removing foreign bodies when it is able to detect the presence of the foreign body, the fractional phototherapy device 100 can be used to resensitize the immune system to the tattoo ink and encapsulation material thereby leading to an immune response. The effect of this stimulation is activation of the normal physiological cascade against a foreign body, leading to its effective removal. Thus, noninflammatory skin conditions can be treated using the methods and apparatuses disclosed herein.

[0086] In an embodiment, exogenous agents can be used to enhance the inflammatory response that removes the tattoo ink particles. The inflammatory response can be enhanced by using antibodies to suppress growth factors and/or by using cytokines, $\text{TNF}\alpha$, IL-1, and/or IL-6 to stimulate a phagocytic response. A second treatment can be used approximately 7 days following the first treatment to release additional bFGF to promote further collagenolytic activity. Rhamnolipids, agents that inhibit fibroblast and keratinocyte proliferation, can be optionally used to prevent wound contraction and scarring at the end of the treatment.

[0087] In another embodiment, stem cells may be administered to the site of treatment, for example, to rejuvenate heart tissue that is either dead or injured. Heart tissue may be treated with fractional phototherapy device 100 to create a particular biological signature that would initiate or accelerate the removal of damaged or dead heart tissue, for example, after a myocardial infarction. Heart stem cells may then be introduced to the treatment site and allow for replacement of the removed tissue.

[0088] Although the detailed description contains many specifics, these should not be construed as limiting the scope of the invention but merely as illustrating different examples and aspects of the invention. It should be appreciated that the scope of the invention includes other embodiments not discussed in detail above. Various other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the method and apparatus of the present invention disclosed herein without departing from the spirit and scope of the invention as defined in the appended claims. Therefore, the scope of the invention should be determined by the appended claims and their legal equivalents. Furthermore, no element, component or method step is intended to be dedicated to the public regardless of whether the element, component or method step is explicitly recited in the claims.

[0089] In the claims, reference to an element in the singular is not intended to mean “one and only one” unless explicitly stated, but rather is meant to mean “one or more.” In addition, it is not necessary for a device or method to address every problem that is solvable by different embodiments of the invention in order to be encompassed by the claims.

[0090] All printed patents and publications referred to in this application are hereby incorporated herein in their entirety by this reference.

Claims

1. A method for modulating the immune response of a subject, the method comprising: contacting a fractional phototherapy device with a target tissue wherein the immune response is modulated, and wherein the target tissue is skin or a visceral organ.
2. The method of claim 1, wherein the fractional phototherapy device emits energy with a wavelength of about 400 nm to about 28,000 nm.
3. The method of claim 1, wherein the fractional phototherapy device emits energy with a wavelength of about 190 nm to about 400 nm.
4. The method of claim 2, wherein the fractional phototherapy device emits energy with a wavelength of about 1300 nm to about 1900 nm.
5. The method of claim 1, wherein the fractional phototherapy device emits energy with a wavelength of about 2000 nm to about 2400 nm.
6. The method of claim 1, wherein the fractional phototherapy device comprises a Nd:YAG laser.
7. The method of claim 1, wherein the fractional phototherapy device comprises a fiber laser.
8. The method of claim 1, wherein the fractional phototherapy device comprises a CO₂ laser, a holmium laser, or an Er:YAG laser, and combinations thereof.
9. The method of claim 1, wherein the fractional phototherapy device comprises an optical source selected from the group consisting of a flashlamp, a dye laser, a diode laser, and an Er:glass laser, and combinations thereof.
10. The method of claim 1, wherein the immune response is modulated for the treatment of inflammatory disease and the target tissue is a visceral organ.
11. The method of claim 1, wherein the immune response is modulated for the treatment of inflammatory disease and the target tissue is skin.
12. The method of claim 1, wherein the immune response is modulated for the treatment of a noninflammatory disease and the target tissue is skin.
13. The method of claim 1, wherein the immune response is modulated for the treatment of acne or psoriasis.
14. The method of claim 1, wherein the immune response is modulated for the treatment of alopecia areata.

15. The method of claim 1, wherein the immune response is modulated for the treatment of vitiligo.
16. A method for treatment of a subject in need thereof, the method comprising:
contacting a fractional phototherapy device with target tissue having a foreign body,
and
modulating the immune response in the target tissue whereby the foreign body is removed, and wherein the target tissue is skin or a visceral organ.
17. The method of claim 16, wherein the target tissue is skin.
18. The method of claim 16, wherein the target tissue is a visceral organ.
19. The method of claim 16, wherein the foreign is completely removed.
20. The method of claim 16, wherein the foreign body is located within dermis of the skin.
21. The method of claim 16, wherein the immune response is amplified by the untreated tissue.
22. The method of claim 16, wherein the immune response is inhibited by the untreated tissue.
23. The method of claim 16, further comprising removal of the foreign body by surgical means.
24. The method of claim 16, further comprising cooling surface of the target tissue.
25. The method of claim 16, further comprising creating a thermal inversion within the target tissue.
26. The method of claim 16, wherein the treatment is proximate to the foreign body.
27. The method of claim 16, wherein the treatment comprising multiple treatments in an interval of about 0.5 minutes to about 10 minutes.
28. The method of claim 16, wherein the treatment creates injury zones.
29. The method of claim 28, wherein the injury zones have a depth to width ratio in the range of about 3:1 to about 10:1.
30. The method of claim 28, wherein the injury zones have a surface area to volume ratio in the range of about $20,000 \text{ m}^{-1}$ to about $100,000 \text{ m}^{-1}$.
31. The method of claim 16, wherein the immune response is localized to within about 10 mm from the target tissue.
32. The method of claim 16, wherein the foreign body comprises skin cancer cells.

33. The method of claim 16, wherein the foreign body comprises tattoo ink particles.
34. The method of claim 16, wherein the foreign body comprises an infection.
35. The method of claim 34, wherein the infection is a fungal infection.
36. The method of claim 16, wherein the foreign body comprises autoimmune disease cells.
37. The method of claim 16, wherein the foreign body comprises human papilloma virus.
38. A method for treatment of a subject in need thereof, the method comprising:
contacting a fractional phototherapy device with target tissue having a foreign body;
administering an exogenous agent to the target tissue; and
modulating the immune response in the target tissue whereby the foreign body is removed, and wherein the target tissue is skin or a visceral organ.
39. The method of claim 38, wherein the exogenous agent is administered topically.
40. The method of claim 38, wherein the exogenous agent is administered systemically.
41. The method of claim 38, wherein the exogenous agent comprises stem cells.
42. The method of claim 38, wherein the exogenous agent comprises homing molecules or targeted stem cells.
43. The method of claim 38, wherein the exogenous agent comprises autologous immunotoxic agents.
44. The method of claim 38, wherein the exogenous agent comprises immunomodulators.
45. The method of claim 38, wherein the exogenous agent comprises a vaccine.
46. The method of claim 38, wherein the exogenous agent comprises cytokines or growth factors, and combinations thereof.
47. The method of claim 38, wherein the exogenous agent comprises paracrine molecules or chemotactic factors, and combinations thereof.

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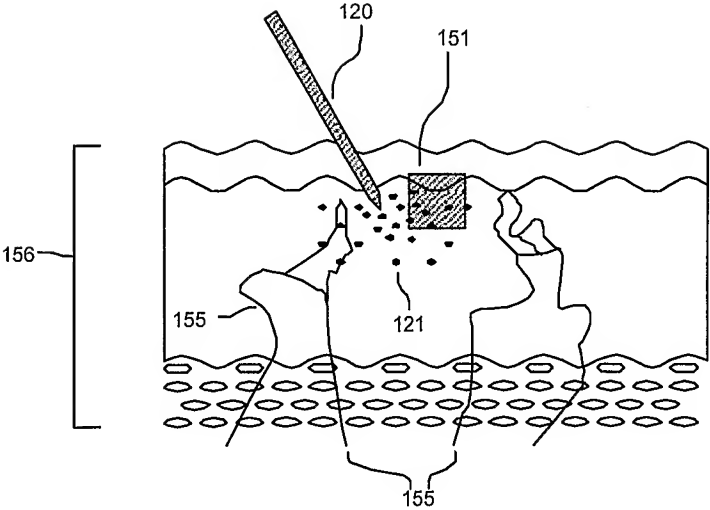


Figure 1A

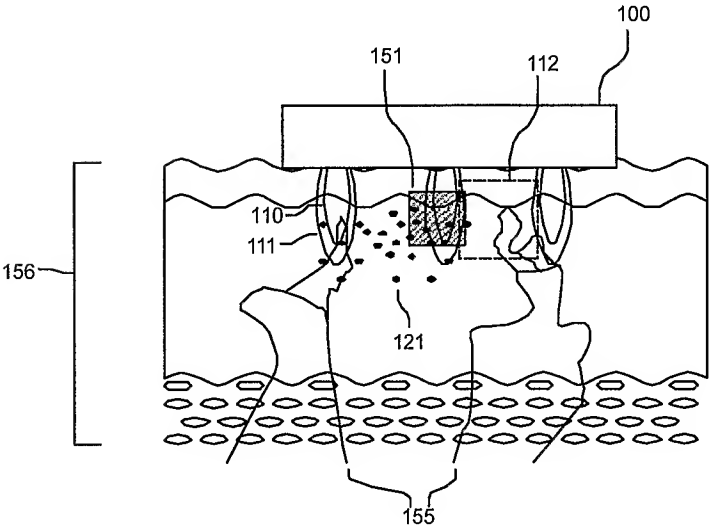


Figure 1B

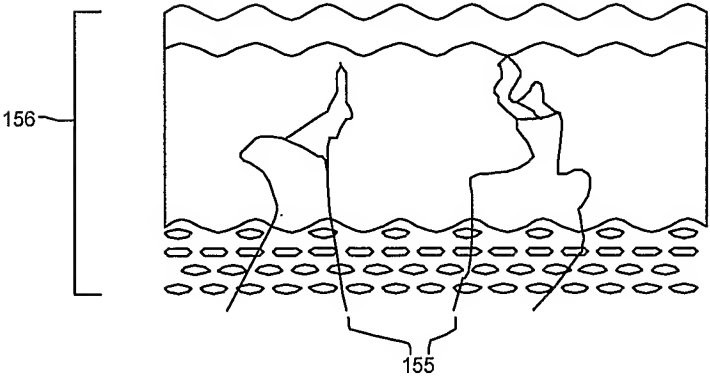


Figure 1C

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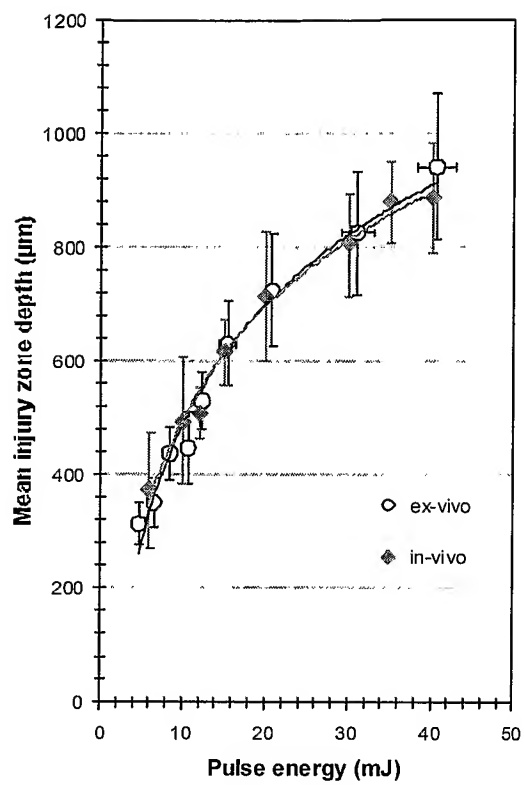


Figure 2A

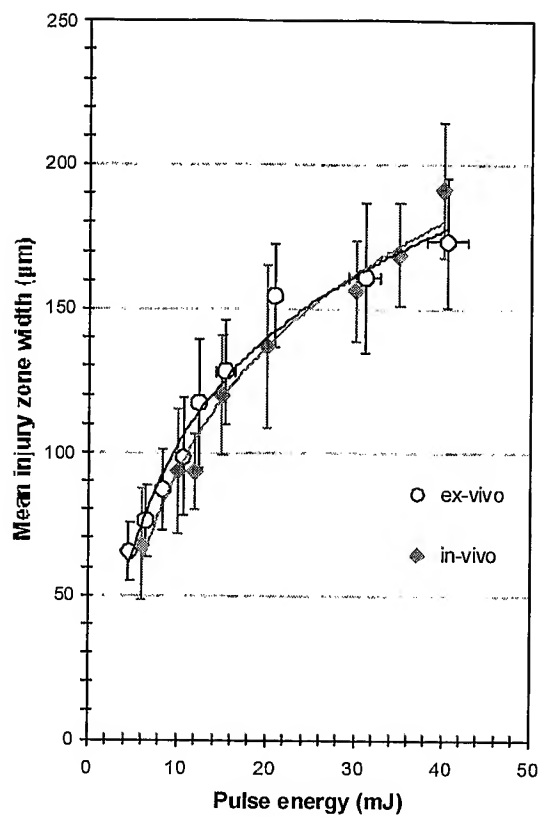


Figure 2B

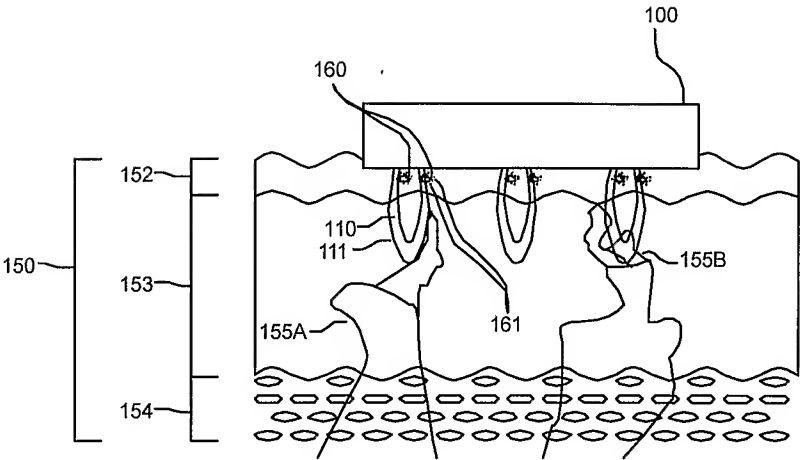


Figure 3A

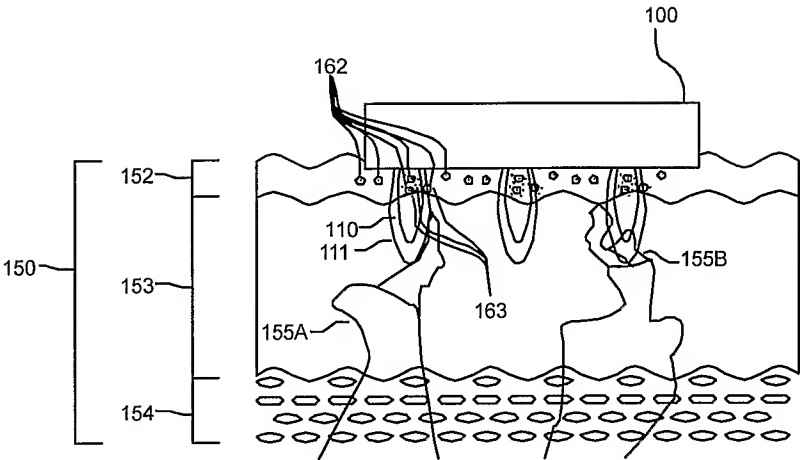


Figure 3B

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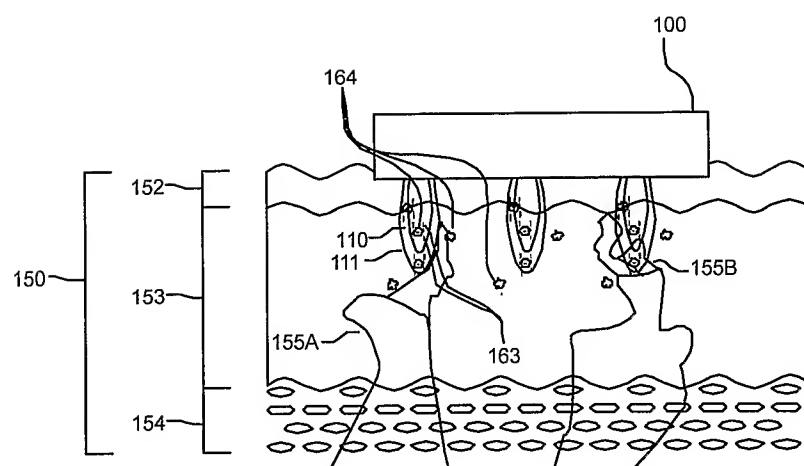


Figure 3C

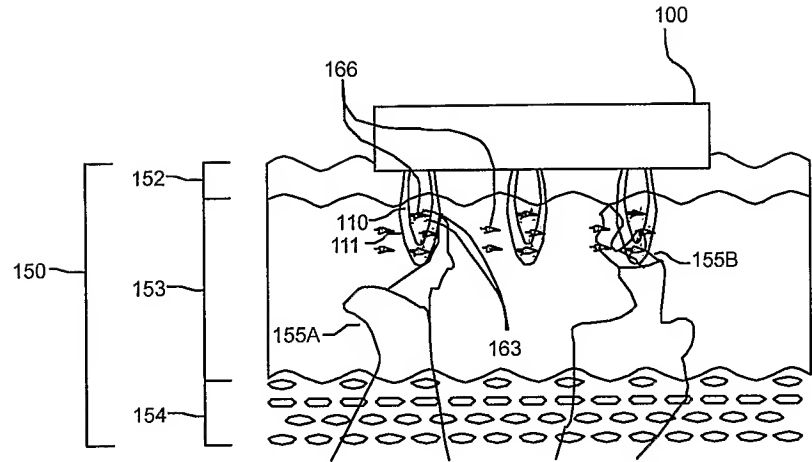


Figure 3D

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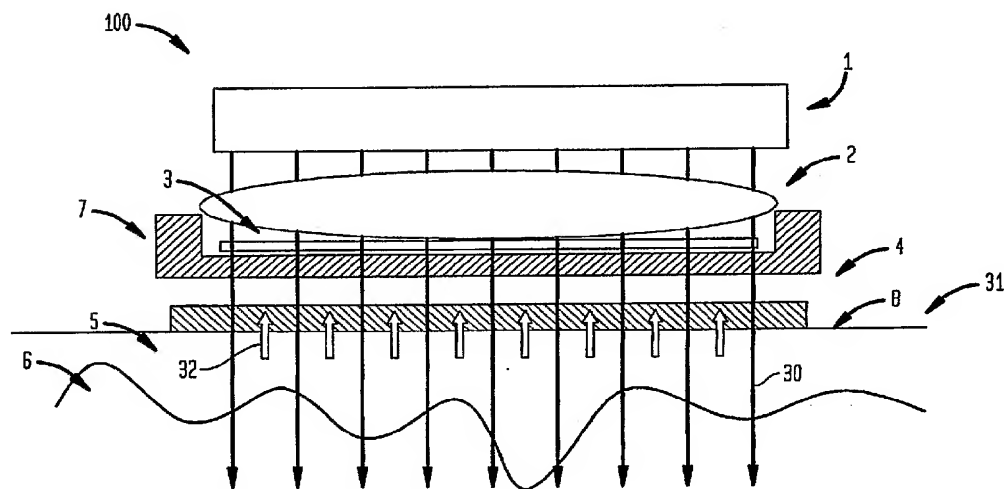
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[Continued on next page]

(54) Title: DERMATOLOGICAL TREATMENT DEVICE



(57) Abstract: A device and method for utilizing optical radiation to treat tissue are described. In one aspect, the device is a dermatological treatment device. The device can be used, for example, for treatment of dermatological and cosmetic conditions. The device can include a sensor that indicates when the device is in contact with a subject's tissue. Operation of the device can, in some instances, be partially or fully automated. The device can further include a light source that is air cooled and a cooling plate that is chilled preferably to 5° C. The device can also include a window that is enlarged to reduce the power density and facilitate heating of tissue at depth.

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RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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DERMATOLOGICAL TREATMENT DEVICE

RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application No. 60/654,130,
5 filed February 18, 2005 entitled *Dermatological Treatment Device*, the contents of
which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

This invention relates generally to methods and apparatus for utilizing energy,
e.g., optical radiation, to treat various dermatological and cosmetic conditions.

10 BACKGROUND OF THE INVENTION

Fractional treatments generally have been directed to treating the epidermis,
which is at the surface of skin tissue. However, for certain applications there is a need to
provide treatments that extend further into the tissue.

Heating tissue at depth can be done with various wavelengths of EMR, both
15 visible and non-visible. Infrared, also known as radiant heat, is a form of energy that
heats objects directly through a process called conversion. Infrared radiation is emitted
by any object that has a temperature (i.e. radiates heat). Infrared is not visible, but can
be felt in the form of heat. The infrared segment of the electromagnetic spectrum occurs
just below or "infra" to red light as the next lowest energy band of light.

20 SUMMARY OF THE INVENTION

One aspect of the invention is a handheld dermatological device that includes a
light source assembly that has a source for generating EMR and a cooling surface that
defines a target treatment area on the tissue when located in proximity to the tissue. The
light source assembly is configured to transmit EMR from the source, and through the
25 cooling surface during operation. The devices also has first cooling mechanism for
cooling the radiation source, and a second cooling mechanism for cooling the cooling
surface.

Preferred embodiments of this aspect of the invention may include some of the
following additional features. The dermatological treatment device can include a fan
30 configured to pump air to cool the source, and a heatsink in thermal communication with

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the source. The fan pumps air over the heatsink to remove heat from the heatsink device during operation. The heatsink includes a plurality of cooling fins. The heatsink is thermally coupled to the source via a reflector, and the fan is configured to cool the source, the reflector, and the heatsink. The handheld dermatological device also has a control unit for controlling the first cooling mechanism. The control unit further includes a controller in electrical communication with a temperature sensor and in electrical communication with the fan, such that the controller can automatically control the first cooling mechanism based on information received from the temperature sensor.

The second cooling mechanism is a circulatory system for circulating a coolant that includes a chiller for cooling the tissue being treated to approximately at least 5° C. The second cooling mechanism also includes a pump, a cooling input, and a cooling output. The cooling input is connected to a cooling window at an input connection and the cooling output is connected to the cooling window at an output connection. The second cooling mechanism is configured to supply cooling fluid to the cooling window during operation via the cooling input and to extract heated coolant from the cooling window via the cooling output to cool the cooling window. The cooling mechanism further includes a chiller.

The second cooling mechanism also includes a temperature sensor for monitoring the temperature of the tissue and a control unit for controlling the second cooling mechanism. The control unit further comprises a controller in electrical communication with a temperature sensor and in electrical communication with the pump. The controller is configured to automatically control the pump based on information received from the temperature sensor.

Another aspect of the invention is a window of a dermatological treatment device that is configured to transmit EMR from a source of the device to tissue being treated. The window has a pane configured to allow EMR to pass from the dermatological treatment device to the tissue being treated. The window also has a first channel extending across substantially across a length of the pane and a frame extending about the pane to secure the pane in the dermatological treatment device. The window includes a first cooling input in fluid communication with a first end of the first channel and a first cooling output in fluid communication with a second end of the first channel. The window is configured to be cooled during operation by fluid traveling through the cooling input, through the first channel and out the second end of the first channel.

Preferred embodiments of this aspect of the invention may include some of the following additional features. The channel of the window is a groove having an open portion extending along a surface of the pane. The window also has an optical surface abutting the surface of the pane such that the groove is enclosed during operation to
5 allow fluid to flow through the channel and to prevent the fluid from flowing out of the open portion. The window also has an optical material between the pane and the optical surface. The material allows some EMR to pass from the dermatological treatment device to the tissue being treated, and can be a dielectric coating.

Another aspect of the invention is a dermatological treatment device for treating
10 tissue located at a depth of at least approximately 0.5 mm. The device includes a housing containing an EMR source and a window. The window is configured to transmit EMR from the source to the tissue being treated. The source is configured to produce at least 500 W of EMR and the window has an area sufficiently large to produce a power density of less than 5 W/cm².

15 Preferred embodiments of this aspect of the invention may include some of the following additional features. The pulse width of the power source is greater than or equal to 0.5 seconds and less than or equal to 600 seconds. The EMR source is configured to produce at least 1000W.

Another aspect of the invention is an apparatus for performing a treatment on
20 tissue, that includes a housing having a cooling surface that defines a target treatment area on the tissue when located in proximity to the tissue, a radiation source for generating EMR that passes through the cooling surface, and a sensor to indicate when the cooling surface is in proximity to the tissue.

Preferred embodiments of this aspect of the invention may include some of the
25 following additional features. Activation of the sensor indicates that the cooling surface contacts the tissue. The sensor can be an e-field sensor, a capacitive sensor, a resistive sensor, a pressure sensor, or an H-field sensor. The sensor can be configured to detect changes in an electrical field.

The sensor is in electrical communication with a controller that is configured to
30 provide signals in response to information obtained from the sensor. The controller issues a first signal corresponding to the detection by the sensor that no tissue is in close proximity and a second signal corresponding to the detection by the sensor that a first tissue is in close proximity. The controller issues a third signal corresponding to the

detection by the sensor that a second tissue is in close proximity to the sensor. The controller distinguishes between tissue types based on the input from the sensor. The controller commands a first action in response to the detection of the first tissue type and a second action in response to the detection of the second tissue type. The first action is to treat the tissue. The second action is to not treat the tissue.

The sensor can include a first node and a second node disposed about the cooling surface. The nodes are in contact with the tissue when the cooling surface is in contact with the tissue and are not in contact with the tissue when the cooling surface is not completely in contact with the tissue. The sensor measures the current between the nodes when in contact with the skin. The sensor indicates that the skin is in contact with the sensor when a current is detected between the nodes.

The sensor can be mounted on the housing, and can be a microswitch. The device also may have an output device operably connected to the sensor. The output device is one of a visual device, an audio device, or a vibrating device. A feedback mechanism may also be connected to the sensor. The feedback mechanism indicates to an operator of the apparatus the amount of time the cooling surface is required to stay in contact with the tissue for safe operation. The feedback mechanism prevents firing of the radiation source if contact of the cooling surface with the tissue is broken. The feedback mechanism prevents firing of the radiation source until after a predetermined cooling time has elapsed.

The device also has a control unit to implement a preset cooling time before allowing firing of the radiation source. The control unit implements a preset firing time for the radiation source. The device can also be a handheld device, and the control unit can be operably coupled to the handheld device.

The radiation source can be a monochromatic source such as a laser. Alternatively, the radiation source can be a halogen lamp, a radiant lamp, an incandescent lamp, an arc lamp, and a fluorescent lamp.

The cooling surface can be made of a deformable or viscoelastic material, like a gel. The cooling surface can also be made of a solid material, such as glass, sapphire or plastic.

The device may have a contact frame that is operably coupled to the housing. The contact frame is movable from an extended position to a retracted position in which it is in proximity to the cooling surface. The sensor activates when the frame is in the

retracted position. The sensor activates when the cooling surface is in proximity to the contact frame. The contact frame has an interior portion that is open to allow passage of EMR. A push rod is connected to the contact frame and is operably coupled to the sensor, such that the push rod activates the sensor when the cooling surface contacts the contact frame. The sensor is mounted on one of the cooling surface and the contact frame.

Another aspect of the invention is an apparatus for performing a treatment on tissue that includes a housing having a means for cooling the tissue. The means for cooling the tissue includes a surface that defines a target treatment area on the tissue when located in proximity to the tissue. The housing also includes a means for generating EMR. The EMR passes through the surface during irradiation. The housing also includes a means for sensing contact of the means for cooling with the tissue.

Preferred embodiments of this aspect of the invention may include some of the following additional features. The means for sensing activates when the means for cooling contacts the contact frame. Activation of the means for sensing indicates that the means for cooling contacts the tissue. A contact frame is operably coupled to the housing. The contact frame is movable from an extended position to a position in which it is in contact with the means for cooling.

Another aspect of the invention is a method of operating a handheld dermatological device, which includes sensing contact of a cooling surface of the handheld device with tissue, indicating to a user of the handheld device when the cooling surface contacts the tissue, and automatically interrupting firing of a radiation source of the handheld device if the cooling surface loses contact with the tissue.

Preferred embodiments of this aspect of the invention may include some of the following additional features. The method can include sensing contact of the cooling surface with tissue, indicating to the user if the cooling surface loses contact with the tissue. The act of sensing contact comprises determining when a contact frame of the handheld device contacts the cooling surface. The contact of the contact frame with the cooling surface indicates contact of the cooling surface with the tissue.

The method may further include distinguishing a first tissue type in contact with the sensor from a second tissue type, and taking an action based on the tissue type. The act of taking an action includes not irradiating the tissue if the tissue corresponds to an untreatable tissue type and irradiating the tissue if the tissue corresponds to a treatable

tissue type. The act of indicating to the user includes activating one of a visual indicator and an audio indicator.

Another aspect of the invention is a method of automatically operating a handheld dermatological device, which includes sensing contact of a cooling surface of the handheld device with tissue, instituting a preset cooling time for cooling of the tissue prior to irradiating the tissue with a radiation source of the handheld device, instituting a preset firing time of the radiation source after the preset cooling time, and interrupting firing of the radiation source if the cooling surface loses contact with the tissue.

Preferred embodiments of this aspect of the invention may include some of the following additional features. The method may further include indicating to the user if the cooling surface loses contact with the tissue, after sensing contact of the cooling surface with tissue. The act of indicating to the user includes activating one of a visual indicator and an audio indicator. The act of sensing contact comprises determining when a contact frame of the handheld device contacts the cooling surface, wherein contact of the contact frame with the cooling surface indicates contact of the cooling surface with the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the present invention will be described by way of example with reference to the accompanying drawings in which:

FIG. 1 is a schematic diagram of one embodiment of the invention, shown in proximity to a tissue sample;

FIG. 2 is a side view of a schematic diagram of part of a handheld dermatological device according to one embodiment of the invention;

FIG. 3 is a second side view of the handheld dermatological device of FIG. 2;

FIG. 4 is a third side view of the handheld dermatological device of FIG. 2;

FIG. 5 is a fourth side view of the handheld dermatological device of FIG. 2;

FIG. 6 is a fifth side view of the handheld dermatological device of FIG. 2;

FIG. 7 is a sixth side view of the handheld dermatological device of FIG. 2;

FIG. 8 is a front view of the handheld dermatological device of FIG. 2;

FIG. 9 is a partial view from the front of a lamp, reflector, and optics of the handheld dermatological device of FIG. 2;

FIG. 10 is a perspective view of the handheld dermatological device of FIG. 2;

FIG. 11 is a second perspective view of the handheld dermatological device of
5 FIG. 2;

FIG. 12 is a back view of the handheld dermatological device of FIG. 2;

FIG. 13 is a second back view of the handheld dermatological device of FIG. 2;

FIG. 14 is a bottom view of the handheld dermatological device of FIG. 2;

FIG. 15 is a side view of the housing structure and complete unit of the handheld
10 dermatological device of FIG. 2;

FIG. 16 is a flow chart that illustrates the operation of one embodiment of the invention.

FIG. 17 is a graph showing the relationship between treatment time and the depth of heating for infrared radiation without pre-cooling the treated tissue; and

15 FIG. 18 is a graph showing the relationship between treatment time and surface skin temperature;

FIG. 19 is a side view of an alternative embodiment of a handheld dermatological device;

FIG. 20 is a cross-sectional side view of the handheld dermatological device of
20 FIG. 19;

FIG. 21 is a schematic top view of a window for use in the handheld dermatological device of FIG. 19;

FIG. 22 is a schematic side view of the window of FIG. 21;

FIG. 23 is a schematic bottom view of an embodiment of a portion of the
25 handheld dermatological device of FIG. 19;

FIGS. 24A and 24B are schematic side views of the portion of the handheld dermatological device shown in FIG. 23 during operation;

FIG. 25 is a schematic side view of an alternate embodiment for a window of a dermatological device;

FIG. 26 is a schematic side view of an alternate embodiment of a waveguide;

FIG. 27 is a bottom view of the waveguide of FIG. 26; and

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FIG. 28 is a bottom view of an alternate embodiment of a face of a dermatological device.

DETAILED DESCRIPTION

The benefits of being able to raise and/or lower the temperature in a selected
10 region of tissue for various therapeutic and cosmetic purposes have been known for
some time. For instance, heated pads or plates or various forms of electromagnetic
radiation (EMR), including microwave radiation, electricity, infrared radiation, and
ultrasound have previously been used for heating subdermal muscles, ligaments, bones
and the like to, for example, increase blood flow, to otherwise promote the healing of
15 various injuries and other damage, and for various therapeutic purposes, such as frostbite
or hyperthermia treatment, treatment of poor blood circulation, physical therapy,
stimulation of collagen, cellulite treatment, adrenergic stimulation, wound healing,
psoriasis treatment, body reshaping, non-invasive wrinkle removal, etc. The heating of
tissues has also been utilized as a potential treatment for removing cancers or other
20 undesired growths, infections and the like. Heating may be applied over a small,
localized area, over a larger area, for example to the hands or feet, or over larger regions
of tissue, including the entire body.

Because most of the techniques described above involve applying energy to
tissue at depth through the subject's skin surface, peak temperature generally occurs at
25 or near the subject's skin surface and decreases, sometimes significantly, with depth.
The radiation is both highly scattered and highly absorbed in surface layers of tissue,
precluding significant portions of such radiation from reaching the tissue regions at
depth to cause heating thereof. In view of the energy losses due to scattering and
absorption, a substantial amount of optical (including near infrared) energy must be
30 applied in order for enough energy to reach a region of tissues at depth to have a desired
effect. However, such a high amount of optical energy can cause damage to the surface
layers of tissue, making it difficult to achieve desired photothermal treatments in tissue

regions at depth. For these reasons, optical radiation has heretofore had at most limited value for therapeutic and cosmetic treatments on tissue at depth.

Methods of deep heating are also desirable for fractional treatments, which depend, in part, upon the discovery that, when using EMR to treat tissues, there are
5 substantial advantages to producing lattices of EMR-treated islets in the tissue rather than large, continuous regions of EMR-treated tissue. The lattices are periodic patterns of islets in one, two or three dimensions in which the islets correspond to local maxima of EMR-treatment of tissue. The islets are separated from each other by non-treated tissue. The EMR-treatment results in a lattice of EMR-treated islets which have been
10 exposed to a particular wavelength or spectrum of EMR, and which is referred to herein as a lattice of "optical islets." When the absorption of EMR energy results in significant temperature elevation in the EMR-treated islets, the lattice is referred to herein as a lattice of "thermal islets." When an amount of energy is absorbed that is sufficient to significantly disrupt cellular or intercellular structures, the lattice is referred to herein as a
15 lattice of "damage islets." By producing EMR-treated islets rather than continuous regions of EMR-treatment, more EMR energy can be delivered while lowering the risk of bulk tissue damage

To more effectively treat tissue with near infrared radiation, the skin at the surface of the tissue is typically cooled to a temperature of approximately 5° C, although
20 other temperatures are used. Thus, the technique of the present invention combines advantageous features of non-ablative and fractional techniques.

Applications in which the invention may be useful include the treatment of various diseases and cosmetic enhancements, particularly, cellulite and subcutaneous fat treatment, physical therapy, muscle and skeletal treatments, including relief of pain and
25 stiffness for muscles and joints, and treatment of spinal cord problems, and treatment of cumulative trauma disorders (CTD's) such as carpal tunnel syndrome (CTS), tendonitis and bursitis, fibromyalgia, lymphedema and cancer therapy and skin rejuvenation treatments, including, for example, skin smoothing, wrinkle and rhytide reduction, pore size reduction, skin lifting, improved tone and texture, stimulation of collagen
30 production, shrinkage of collagen, reduction of skin dyschromia (i.e. pigment non-uniformities), reduction telangiectasia (i.e. vascular malformations), improvement in skin tensile properties (e.g. increase in elasticity, lifting, tightening), treatment of acne,

hypertrophic scars, reducing body odor, removing warts and calluses, treating psoriasis, and decreasing body hair.

The present invention provides means for effective deep heating of tissue using both fractional and non-fractional procedures. For fractional procedures, the
5 embodiments described below may create non-uniform (modulated) temperature profiles (MTP), including deep in the dermis and in hypodermis (typically, at depths exceeding 500 μm) or superficially in the epidermis and/or dermis. In some embodiments, such profiles result in formation of a pattern (lattice) of islets of damage (LID). Active or passive cooling can be applied to epidermal surface in order to prevent epidermal
10 damage.

Creation of MTPs leads to improvements in skin structure and texture via the following mechanisms (the list is not exclusive):

1. Lifting and tightening of skin as a result of shrinkage of collagen fibrils subjected to elevated temperature.
- 15 2. Lifting and tightening of skin as a result of coagulation of localized areas in the dermis and hypodermis.
3. Improvement in skin texture as a result of coagulation of localized areas in the dermis and hypodermis.
4. Promotion of collagen production due to healing response to thermal stress
20 and/or thermal shock.

A number of other local and systemic pathologies can be treated with the technique:

1. Cellulite: By changing mechanical stress distribution at the dermis/hypodermis border, the appearance of cellulite can be improved.
- 25 2. Acne: By selecting the wavelength of the optical radiation to promote preferential absorption of the optical energy by sebum and/or organizing the pattern to target preferentially sebaceous glands, selective destruction of the glands can be achieved.
3. Hypertrophic scars: By inducing tightening and shrinkage in the scar tissue,
30 transformation of the abnormal connective tissue to normal one can be initiated.
4. Odor reduction: By selectively targeting eccrine glands, production of eccrine sweat can be reduced, and its composition can be changed.

5. Non-skin-surface texturing: The technique can be used for organ augmentation (e.g., lips).

One embodiment of the invention is a handheld dermatological device that incorporates a mechanism for cooling a subject's skin surface concurrently with the application of optical radiation thereto. While the radiation reaches the tissue at depth to be treated quickly to begin the heating thereof, cooling propagates as a cold wave, protecting tissue above the treatment region and moving the depth of maximum heating further into the skin. In one embodiment, the cooling wave can propagate to a depth just above the treatment region, but does not extend to the treatment region at least until sufficient energy has been delivered to the treatment region to effect the desired treatment. The cooling mechanism of the device can cool the subject's skin prior to, during, and/or after the application of radiation thereto to more effectively protect tissue above the treatment region and to insure that the maximum temperature rise in the irradiated tissue occurs at or near a desired depth. This may also permit higher energy and shorter duration of radiation pulses to be applied to the skin without any damage or minimal damage to tissue above the desired depth. The head used to apply the radiation may also be used to apply cooling. The handheld dermatological device can include a sensor mounted adjacent the cooling mechanism near the subject's skin. Such a sensor can indicate when the cooling mechanism contacts the subject's skin (or loses contact with the subject's skin), thus indicating to the user when it is safe to begin application of radiation.

Figure 1 shows an apparatus 100 according to one embodiment of the invention. For this apparatus, optical energy 30 from a suitable energy source 1 passes through optical (for example, focusing) device 2, filter 3, cooling mechanism 4 and contact plate 8, before reaching tissue 31 (i.e., the subject's skin). In some embodiments of the invention, certain of these components, such as, for example, filter 3 where a monochromatic energy source is utilized or optical device 2, may not necessarily be present. In other embodiments, the apparatus may not contact the skin. In yet another embodiment, there is no cooling mechanism 4 such that there is only passive cooling between the contact plate and the skin.

A suitable optical impedance matching lotion or other suitable substance would typically be applied between plate 8 and tissue 31 to provide enhanced optical and

thermal contact. Tissue 31, as shown in FIG. 1, is divided into an upper region 5, which, for applications where radiation is applied to the skin surface, would be the epidermis and dermis, and a lower region 6, which would be a subdermal region in the previous example. Region 6, for instance, can be the hypodermis.

5 Energy 30, possibly in conjunction with one or a combination of focusing from optical device 2, and wavelength selection from filter 3, and with cooling from cooling mechanism 4, results in maximum heating occurring at a selected depth in tissue 31. The selected depth can be, as previously indicated, at or near the junction of regions 5 and 6 or in lower region 6, and it can also be in region 5 or in the hypodermis.

10 The energy source 1 may be any suitable electromagnetic radiation (EMR) source, but will preferably be a source emitting visible light, or energy in the near infrared and infrared ranges. The light sources used in conjunction with the invention may be coherent and non-coherent sources, able to produce optical energy at a desired wavelength or a desired wavelength band or in multiple wavelength bands. The exact
15 energy source 1, and the exact energy chosen, may be a function of the type of treatment to be performed, the tissue to be heated, the depth within the tissue at which treatment is desired, and of the absorption of that energy in the desired area to be treated. Energy source 1 may produce EMR, such as near infrared or visible light radiation over a broad spectrum, over a limited spectrum, or at a single wavelength, such as would be produced
20 by a light emitting diode or a laser. In certain cases, a narrow spectral source may be preferable, as the wavelength(s) produced by the energy source may be targeted towards a specific tissue type or may be adapted for reaching a selected depth. In other embodiments, a wide spectral source may be preferable, for example, in systems where the wavelength(s) to be applied to the tissue may change, for example, by applying
25 different filters, depending on the application. Acoustic, RF or other EMF sources may also be employed in suitable applications.

 For example, UV, violet, blue, green, yellow light or infrared radiation (*e.g.*, about 290-600 nm, 1400 – 3000 nm) can be used for treatment of superficial targets, such as vascular and pigment lesions, fine wrinkles, skin texture and pores. Blue, green,
30 yellow, red and near IR light in a range of about 450 to about 1300 nm can be used for treatment of a target at depths up to about 1 millimeter below the skin. Near infrared light in a range of about 800 to about 1400 nm, about 1500 to about 1800 nm or in a

range of about 2050 nm to about 2350 nm can be used for treatment of deeper targets (e.g., up to about 3 millimeters beneath the skin surface). The following table shows examples of the wavelengths of electromagnetic energy that are thought to be suitable for treating various cosmetic and medical conditions.

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TABLE 1: Uses of Light of Various Wavelengths In Photocosmetic Procedures

Treatment condition or application	Wavelength of Light, nm
Anti-aging	400 -2700
Superficial vascular	290-600 1300-2700
Deep vascular	500-1300
Pigmented lesion, de pigmentation	290-1300
Skin texture, stretch mark, scar, porous	290-2700
Deep wrinkle, elasticity	500-1350
Skin lifting	600-1350
Acne	290-700, 900-1850
Psoriasis	290-600
Hair growth control	400-1350
PFB	300-400, 450-1200
Cellulite	600-1350
Skin cleaning	290-700
Odor	290-1350
Oiliness	290-700, 900-1850
Lotion delivery into the skin	1200-20000
Color lotion delivery into the skin	Spectrum of absorption of color center and 1200-20000
Lotion with PDT effect on skin condition including anti cancer effect	Spectrum of absorption of photo sensitizer
ALA lotion with PDT effect on skin condition including anti cancer effect	290-700
Pain relief	500-1350
Muscular, joint treatment	600-1350
Blood, lymph, immune system	290 – 1350
Direct singlet oxygen generation	1260-1280

The energy source 1 can be any variety of a coherent light source, such as a solid-state laser, dye laser, diode laser, fiber laser, or other coherent light source. For example, energy source 1 may be a radiant lamp, a halogen lamp, an incandescent lamp, an arc lamp, a fluorescent lamp, a light emitting diode, a laser (including diode and fiber lasers), the sun, or other suitable optical energy source. As another example, the energy

10

source 1 can be a neodymium (Nd) laser, such as a Nd:YAG laser. In addition, multiple energy sources may be used which are identical or different. For example, multiple laser sources may be used and they may generate optical energy having the same wavelength or different wavelengths. As another example, multiple lamp sources may be used and they may be filtered to provide the same or different wavelength band or bands. In addition, different types of sources may be included in the same device, for example, mixing both lasers and lamps.

In this exemplary embodiment, the energy source 1 includes a neodymium (Nd) laser generating radiation having a wavelength around 1064 nm. Such a laser includes a lasing medium, *e.g.*, in this embodiment a neodymium YAG laser rod (a YAG host crystal doped with Nd⁺³ ions), and associated optics (*e.g.*, mirrors) that are coupled to the laser rod to form an optical cavity for generating lasing radiation. In other embodiments, other laser sources, such as chromium (Cr), Ytterbium (Yt) or diode lasers, or broadband sources, *e.g.*, lamps, can be employed for generating the treatment radiation.

Lasers and other coherent light sources can be used to cover wavelengths within the 100 to 100,000 nm range. Examples of coherent energy sources are solid state, dye, fiber, and other types of lasers. For example, a solid state laser with lamp or diode pumping can be used. The wavelength generated by such a laser can be in the range of 400 – 3,500 nm. This range can be extended to 100 – 20,000 nm by using non-linear frequency converting. Solid state lasers can provide maximum flexibility with pulse width range from femtoseconds to a continuous wave.

Another example of a coherent source is a dye laser with non-coherent or coherent pumping, which provide wavelength-tunable light emission. Dye lasers can utilize a dye dissolved either in liquid or solid matrices. Typical tunable wavelength bands cover 400 – 1,200 nm and a laser bandwidth of about 0.1 – 10 nm. Mixtures of different dyes can provide multi wavelength emission. Dye laser conversion efficiency is about 0.1 – 1 % for non-coherent pumping and up to about 80 % with coherent pumping.

Another example of a coherent source is a fiber laser. Fiber lasers are active waveguides with a doped core or undoped core (Raman laser), with coherent or non-coherent pumping. Rare earth metal ions can be used as the doping material. The core and cladding materials can be quartz, glass or ceramic. The core diameter could be from

microns to hundreds of microns. Pumping light could be launched into the core through the core facet or through cladding. The light conversion efficiency of such a fiber laser could be up to about 80% and the wavelength range can be from about 1,100 to 3,000 nm. A combination of different rare-earth ions, with or without additional Raman
5 conversion, can provide simultaneous generation of different wavelengths, which could benefit treatment results. The range can be extended with the help of second harmonic generation (SHG) or optical parametric oscillator (OPO) optically connected to the fiber laser output. Fiber lasers can be combined into the bundle or can be used as a single fiber laser.

10 Diode lasers can be used for the 400 –100,000 nm range. Since many photodermatology applications require a high-power light source, the configurations described below using diode laser bars can be based upon about 10 –100 W, 1-cm-long, cw diode laser bar. Note that other sources (*e.g.*, LEDs and microlasers) can be substituted in the configurations described for use with diode laser bars with suitable
15 modifications to the optical and mechanical sub-systems.

Other types of lasers (*e.g.*, gas, excimer, etc.) can also be used.

A variety of non-coherent sources of EMR (*e.g.*, arc lamps, incandescence lamps, halogen lamps, light bulbs) can be used in the invention for the energy source 1. There are several monochromatic lamps available such as, for example, hollow cathode
20 lamps (HCL) and electrodeless discharge lamps (EDL). HCL and EDL could generate emission lines from chemical elements. For example, sodium emits bright yellow light at 550 nm.

Linear arc lamps use a plasma of noble gases overheated by pulsed electrical discharge as a light source. Commonly used gases are xenon, krypton and their mixtures,
25 in different proportions. The filling pressure can be from about several torr to thousands of torr. The lamp envelope for the linear flash lamp can be made from fused silica, doped silica or glass, or sapphire. The emission bandwidth is about 180-2,500 nm for clear envelope, and could be modified with a proper choice of dopant ions inside the lamp envelope, dielectric coatings on the lamp envelope, absorptive filters, fluorescent
30 converters, or a suitable combination of these approaches.

In some embodiments, a Xenon-filled linear flash lamp with a trapezoidal concentrator made from BK7 glass can be used. As set forth in some embodiments below, the distal end of the optical train can, for example, be an array of microprisms attached to the output face of the concentrator. The spectral range of EMR generated by
5 such a lamp can be about 300 – 2000 nm.

Incandescent lamps are one of the most common light sources and have an emission band from 300 to 4,000 nm at a filament temperature of about 2,500 C. The output emission can be concentrated on the target with reflectors and/or concentrators.

Halogen tungsten lamps utilize the halogen cycle to extend the lifetime of the
10 lamp and permit it to operate at an elevated filament temperature (up to about 3,500 C), which greatly improves optical output. The emission band of such a lamp is in the range of about 300 to 3,000 nm.

Light-emitting diodes (LEDs) that emit light in the 290-2,000 nm range can be used to cover wavelengths not directly accessible by diode lasers.

15 Where optical device 2 is a focusing device, it may be any suitable device able to focus at least a portion of energy 30 arriving from energy source 1 at tissue 31, and in particular at a selected depth in tissue 31. For example, device 2 may include mirrors, prisms, reflectors, lenses such as Fresnel lenses, collimating lenses or focusing lenses, diffraction gratings, or other optical devices. Device 2 may also include a plurality or an
20 array of devices listed above.

Filter 3 may be any suitable filter able to select, or at least partially select, certain wavelengths or wavelength bands from energy source 1. In certain embodiments, a specific set of wavelengths may be blocked by filter 3. It is also possible that undesired wavelengths in the energy from source 1 may be wavelength shifted in ways known in
25 the art so as to enhance the energy available in the desired wavelength bands. Thus, filter 3 may include elements designed to absorb, reflect or alter certain wavelengths of electromagnetic radiation. For example, filter 3 may be used to remove certain types of wavelengths that are absorbed by surrounding tissues. For instance, dermis, hypodermis and epidermis tissues are primarily composed of water, as is much of the rest of the
30 human body. By using a filter that selectively removes wavelengths that excite water molecules, the absorption of these wavelengths by the body may be greatly reduced,

which may contribute to a reduction in the amount of heat generated by light absorption in these molecules. Thus, by passing radiation through a water-based filter, those frequencies of radiation that may excite water molecules will be absorbed in the water filter, and will not be transmitted into tissue 31. Thus, a water-based filter may be used
5 to decrease the amount of radiation absorbed in tissue above the treatment region and converted into heat. For other treatments, absorption of the radiation by water may be desired or required for treatment.

Figure 1 shows a cooling mechanism 4 adjacent to the surface of tissue 31. Cooling mechanism 4 may be any suitable cooling mechanism able to reduce the
10 temperature of tissue 31. Heat energy 32 may be drawn from tissue 31 across contact plate 8 into cooling mechanism 4. For example, cooling mechanism 4 may be air or other suitable gas that is blown over contact plate 8, cooling water, or a cooling oil or other fluid. Mixtures of these substances, such as an oil and water mixture, may also be envisioned. Cooling mechanism 4 may have any suitable configuration, for example, a
15 flat plate, a series of conducting pipes, a sheathing blanket, or a series of channels for the passage of air, or other gases, or liquid across plate 8. For example, in one embodiment, cooling mechanism 4 may be a water-cooled contact plate. In another embodiment, cooling mechanism 4 may be a series of channels carrying a coolant fluid or a refrigerant fluid (for example, a cryogen), which channels are in contact with tissue 31 or with plate
20 8. In yet another embodiment, cooling mechanism 4 may comprise a water or refrigerant fluid (for example R134A) spray, a cool air spray or air flow across the surface of tissue 31. In other embodiments, cooling may be accomplished through chemical reactions (for example, endothermic reactions), or through electronic cooling, such as Peltier cooling. In yet other embodiments, cooling mechanism 4 may have more
25 than one type of coolant, or cooling mechanism 4 and/or contact plate 8 may be absent, for example, in embodiments where the tissue is cooled passively or directly, for example, through a cryogenic or other suitable spray. Sensors or other monitoring devices may also be embedded in cooling mechanism 4, for example, to monitor the temperature, or determine the degree of cooling required by tissue 31, and be manually
30 or electronically controlled.

In certain cases, cooling mechanism 4 may be used to maintain the surface temperature of tissue 31 at its normal temperature, which may be, for example, 37 or 32

°C, depending on the type of tissue being heated. In other embodiments, cooling mechanism 4 may be used to decrease the temperature of the surface of tissue 31 to a temperature below the normal temperature of that type of tissue. For example, cooling mechanism 4 may be able to decrease the surface temperature of tissue 31 to, for example, a range between 25 °C and -5 °C.

In some embodiments of the invention, such as shown in FIG. 1, energy 30 from energy source 1 may pass through cooling mechanism 4. In these types of configurations, cooling mechanism 4 may be made from materials able to transmit at least a portion of energy 30, for example, air, water or other gases or fluids, glass, or a clear plastic. In other embodiments, cooling mechanism 4 may be formed out of a series of discrete channels, and energy 30 may pass between these channels. In other embodiments of the invention, energy 30 may not be directed through cooling mechanism 4.

Contact plate 8 may be made out of a suitable heat transfer material, and also, where the plate contacts tissue 31, of a material having a good optical match with the tissue. Sapphire is an example of a suitable material for plate 8. In some embodiments, contact plate 8 may have a high degree of thermal conductivity, for example, to allow cooling of the surface of the tissue by cooling mechanism 4. In other embodiments, contact plate 8 may be an integral part of cooling mechanism 4, or be absent. Contact plate 8 may be made out of a deformable or viscoelastic material in some embodiments of the invention, for example, a gel such as a hydrogel. In other embodiments, contact plate 8 may be made of a solid material, such as a glass, a crystal such as sapphire, or a plastic. In some embodiments of the invention, such as shown in FIG. 1, energy 30 from energy source 1, or a fraction thereof, may pass through contact plate 8. In these configurations, contact plate 8 may be made out of materials able to transmit at least a portion of energy 30, for example glass, sapphire, or a clear plastic, or contact plate 8 may be made in such a way as to allow at least a portion of energy 30 to pass through contact plate 8, for example, via a series of holes, passages, lenses, etc. within contact plate 8.

In some embodiments of the invention, energy source 1, optical device 2 and/or filter 3 may also require a cooling mechanism. This cooling mechanism may or may not be the same as the cooling mechanism 4 that cools tissue 31 through contact plate 8, as

indicated by arrows 32 in FIG. 1. For example, in the embodiment shown in FIG. 1, cooling mechanism 7, shown separately from cooling mechanism 4, is used to cool filter 3 and/or optical device 2. The design of cooling mechanism 7 may be a function of the components used in the construction of the apparatus. In FIG. 1, cooling mechanism 7 and cooling mechanism 4 are illustrated as separate systems. However, in other embodiments, cooling mechanism 7 and cooling mechanism 4 may be part of the same system, or one or both may be absent. Cooling mechanism 7 may be any suitable cooling mechanism known in the art, such as air, water, or oil. Mixtures of these substances, such as an oil and water mixture, may also be envisioned. Cooling of the components may be accomplished through convective or conductive cooling.

One or more of energy source 1, optical device 2, filter 3, cooling mechanism 4, or cooling mechanism 7 may be electronically controlled. For example, sensors embedded in cooling mechanism 4 or contact plate 8 may determine the amount of energy reaching tissue 31, and may direct energy source 1 to produce more or less energy or may direct cooling mechanism 4 to increase or decrease cooling, depending on the application. Other sensors and the like may be embedded in any of the components illustrated herein. The controls may be, for example, electronically preprogrammed, or manually operable.

Figure 2 is a side cross-sectional view of the handheld dermatological device 200 according to this embodiment of the invention. Figure 2 illustrates most of the components of one embodiment of the handheld dermatological device 200. Figure 15, on the other hand, is a side view of the complete handheld dermatological device 200, in a housing 300, according to one embodiment of the invention. Figures 3-14 are views of the handheld dermatological device 200 of FIG. 2 from varying angles, and these figures illustrate embodiments of the handheld dermatological device 200 in different states of construction. That is, FIGS. 3-14 do not depict the entire handheld dermatological device 200, including all of its components, in its housing 300.

In the embodiment of FIGS. 2-15, a handheld dermatological device 200 includes many of the features discussed above in connection with FIG. 1. Referring to FIG. 2, the device 200 includes an energy source 202, which may be any suitable optical energy source able to produce optical energy at a wavelength that produces heating within tissue at the depth of a desired treatment region. In the embodiment of FIG. 2,

the energy source 202 is, for example, a tungsten halogen lamp. Disposed above and in surrounding relation to the energy source 202 is a reflector 206. The reflector 206 serves to reflect energy from the energy source 202 (e.g. downward) toward skin contact plate 210. In other embodiments of the invention, such a reflector 206 is not used. In
5 the embodiment of FIGS. 2, 8, and 9, the reflector 206 approximately semi-circular in cross-section (FIGS. 8, 9) and has a tubular length (FIG. 2). The reflector 206 can be made from any material known to reflect radiation, such as, for example, a metal. Preferably, the surface of reflector 206 is gold, although any highly reflective metal can be used, including silver or copper.

10 Disposed between the energy source 202 and the skin contact plate 210 in the embodiment of FIG. 2 is an optical device 204 and/or a filter (not shown). The optical device 204 can be a focusing device to focus at least a portion of energy from energy source 202 at tissue disposed below the device 200, and in particular at a selected depth in tissue. Optical device 204 may also be a waveguide, preferably made of quartz. The
15 filter, if used, can be any suitable filter able to select, or at least partially select, certain wavelengths or wavelength bands from energy source 202. The optical device 204 and the filter, if used, can be the same as those discussed above in connection with the embodiment of FIG. 1.

In the embodiment of FIGS. 2-15, the handheld device 200 includes a cooling
20 mechanism 208 disposed at a distal tip for application to the subject's skin or tissue. Such a cooling mechanism 208 can include a contact plate 210 to contact the subject's skin and a jacket 212 to hold the contact plate 210. The contact plate 210 can be made out of a suitable heat transfer material, such as those set forth above. The contact plate 210 can allow the radiation from the energy source 202 to pass through it in order to
25 irradiate the subject's skin. In other embodiments, a mask, screen or shield (not shown), incorporated within or disposed above or below the contact plate 210 within the device 200, can block some of the radiation from reaching the subject's skin, thus creating selected areas of treatment on the subject's skin. In still other embodiments, an array of focusing elements (e.g., lenses, prisms) can be incorporated within or disposed above or
30 below the contact plate 210 within the device 200 to focus or disperse the radiation to certain locations in the skin, thus creating selected areas of treatment on the subject's skin. (A further description of such methods and apparatus are disclosed in U.S. Patent

No. 6,997,923, issued February 14, 2006 and assigned to Palomar Medical Technologies, Inc. US Patent No. 6,997,923 is incorporated herein by reference.)

In one embodiment, the contact plate 210 is made from sapphire. The cooling mechanism 208 can also include a jacket 212 disposed at the tip of the device 200 to hold the contact plate 210. In one embodiment, the jacket 212 can be a metal structure disposed around the contact plate 210. The jacket 212 can have an opening through its middle to allow for passage of radiation through the jacket 212. In the embodiment of FIGS. 2-15, the jacket 212 is configured to receive a coolant, such as water, air, or oil, which can circulate within the jacket 212 to remove heat from the jacket 212 and contact plate 210. The device 200 of FIGS. 2-15 also includes a cooling manifold 214 to supply coolant to the jacket 212. Alternatively, optical device 204 can be a waveguide which passes through jacket 212 such that one end of the waveguide provides contact surface 210. In use, the contact plate 210 defines the target treatment area on the subject's tissue.

The handheld device 200 can include a sensing mechanism 220 to indicate when the contact plate 210 contacts the subject's skin. The sensing mechanism 220 includes a contact frame 222, push rods 224, and a sensor 226. Sensor 226 can, for example, be a micro-switch. FIGS. 2-15 illustrate an embodiment of the invention, which incorporates a sensing mechanism 220 to sense contact of the cooling mechanism to the subject's skin. Sensing mechanism 220 is mounted adjacent the cooling mechanism and near the subject's skin. Such a sensing mechanism 220 can indicate when the cooling mechanism contacts the subject's skin and/or when the cooling mechanism loses contact with the subject's skin. Such a sensing mechanism 220 can also, in one embodiment, be incorporated within the apparatus 100 of FIG. 1.

The contact frame 222 can have a rectangular cross-section, as shown in the embodiment of FIGS. 10-11. In other embodiments, the contact frame 222 can have a square or circular cross-section, or any other desired shape. As shown in FIGS. 10-11, the contact frame 222 can be shaped as a frame so that an interior portion of the frame 222 is open. Thus, radiation from the energy source 202 can be applied to the subject's skin through the interior portion of the contact frame 222. The contact frame 222 can be made from metal, plastic, or any other suitable materials.

The sensor 226 is a device that senses when the contact surface 210 touches the subject's skin. More particularly, the sensor 226 senses when the contact frame 222 touches the contact surface 210 of the cooling mechanism 208, which indicates that the contact surface 210 is in contact with the subject's skin. The sensor 226 can be any
5 mechanical, optical, electro-optical, or other sensor that indicates contact of the contact surface 210 to the subject's skin. In one embodiment, the sensor 226 can be a micro-switch. The sensor 226 can be calibrated so that it is activated when the contact surface 210 touches the contact frame 222.

In the embodiment of FIGS. 2-15, the push rods 224 operably connect the
10 contact frame 222 to the sensor 226. In the illustrative embodiment, two push rods 224 are connected to the contact frame 222. In this embodiment, both push rods 224 connect to one side of the contact frame 222. In other embodiments, the push rods 224 can be disposed on different sides of the contact frame 222. In other embodiments, only a single push rod 224 can be used. In still other embodiments, more than two push rods
15 224 can be used. In the embodiment of FIGS. 2-15, the push rods 224 contact the sensor 226, activating it, when the contact frame 222 contacts the contact surface 210 of the cooling mechanism 208.

The contact frame 222, push rods 224, and sensor 226 of the contact mechanism 220 can be operably connected to the device 200. In the illustrative embodiment of
20 FIGS. 2-15, for example, the contact frame 222 is connected to the push rods 224, which in turn are connected through housing 300 and links (not shown) to the lower portion of the device 200. Such a link or links secures the push rods 224, and therefore also the contact frame 222, to the device 200, while allowing the push rods 224 and contact frame 222 to move up and down with respect to the device 200. As shown in FIGS. 3, 4,
25 and 15 by a double-headed arrow, the contact frame 222 can move up and down with respect to the contact plate 210. The sensor 226 can, in one embodiment, be securely mounted to a housing 300 of the device 200. In another embodiment, sensor 226 can be located between the contact frame 222 and the contact plate 210, by being securely mounted to the contact frame 222 or the contact plate 210. In this embodiment, the
30 sensor 226 is activated upon contact of the contact plate 210 with the contact frame 222. The contact mechanism 220 can also include, in some embodiments, a spring or other

device to bias the contact frame 222 away from the contact plate 210 of the cooling mechanism 208.

In another embodiment of the invention, the sensor 226 can provide feedback to the user to indicate contact of the cooling plate 210, or the lack of such contact, with the subject's skin. In one embodiment, the sensor 226 can have an output on the handheld device 200. For example, the handheld device 200 can include a visual indicator, such as a light, that indicates when the contact plate 210 is in contact with the subject's skin. For instance, if the light is on, that can indicate that the contact plate 210 is in contact with the subject's skin, and if the light is off, that can indicate that the contact plate 210 is not in contact with the subject's skin. The handheld device 200 can, in other embodiments, include a speaker or other audio device to communicate to the user that the contact plate 210 is in contact with the subject's skin. The audio device can, in one embodiment, beep to indicate contact with the skin. In addition, the audio device can beep to indicate that contact of the cooling plate 210 with the skin has ended. In another embodiment, the audio device can produce a continuous tone during the entire period in which the contact plate 210 is in contact with the subject's skin. When the contact with the skin is broken, for instance, the sound can end. In another embodiment, tactile feedback can be provided to the user, for example, the handheld device 200 may vibrate when the contact plate 210 is in contact with the subject's skin.

In another embodiment, the sensor 226 of the sensing mechanism 220 can be electrically or optically connected through the cable (or connector 216) to the control unit (not shown). FIG. 2, for instance, depicts a wire 230 or cord that is connected at one end to the sensor 226. The other end of this wire 230 can be connected to the control unit through the connector 216. Thus, a visual and/or audio and/or tactile indicator, similar to those described above, can be produced at the control unit to indicate contact (or the lack thereof) of the cooling mechanism 208 with the subject's skin.

In one embodiment, the handheld device 200 of FIGS. 2-15 includes a connection 216 (FIGS. 3, 4) for an umbilical cord or cable connection to a control or base unit (not shown) that can communicate through control signals with the handheld device 200. The control unit can include, for example, a supply of coolant for the cooling mechanism 208. FIG. 2, for instance, depicts the cooling manifold 214

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connecting the jacket 212 to the connection 216 for the umbilical cord. In another embodiment, the control unit can include power settings and the like for the energy source 202 within the handheld device 200. In addition, the control unit can include a microcomputer and/or a controller to control certain features of the invention, as will be described below in greater detail. The cable connecting the control unit to the connection 216 of the handheld device 200 can include supply lines for coolant and wires for control and power of the handheld device 200. In other embodiments, such a connection 216 might not be used.

Another embodiment of the invention is an air cooling mechanism and process for the handheld device 200. Referring to FIGS. 2-15, and more particularly to FIGS. 10-11, one example of an air cooling mechanism includes a fan 240 and a manifold 242. In one embodiment, the fan 240 can be an electrical fan supplied with power through the cable from the control unit. In addition, in some embodiments, the power (i.e., speed) of the fan can be controlled through the control unit. Any type of fan 240 can be used within the scope of the invention. In the embodiment of FIGS. 2-15, the fan 240 is compact enough to fit within the housing 300 of the handheld device 200.

In the embodiment of FIGS. 2-15, a manifold 242 surrounds the items within the handheld device 200 that require cooling. For instance, the energy source 202 and the reflector 206 may require cooling. In addition, numerous other parts within the device 200 might require cooling, such as the optical device 204, electrodes, and/or other reflecting surfaces within the device 200. The manifold 242 can be configured to supply cooling to such areas.

In the embodiment of FIGS. 2-15, the manifold 242 includes a plurality of fins 244. These fins 244 increase the cooling surface area of the manifold 242, which increases the cooling capacity of the device 200. The manifold 242 can be made from metal or any other suitable material. In addition to or in place of the fins 244, the manifold 242 can include one or more radiators of different types that aid in removing heat from the device 200. The manifold 242 can also include fins 244 or radiators that extend near any of the structures that require cooling. The fins 244 can extend in any direction, including upward as shown in FIGS. 10-11.

The fan 240 blows air through the manifold 242, removing heat from the manifold 242 and causing the device 200 to stay cool. With the incorporation of a fan

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240 of sufficiently small size and sufficiently high power, such a cooling mechanism can efficiently remove heat from the handheld device 200 in a cost effective manner, without sacrificing size.

5 The embodiment of the invention depicted in FIGS. 2-15 uses air cooling for the energy source 202 and reflector 206, and it uses water cooling for the cooling mechanism 208 for contact with the subject's skin. In other embodiments, air cooling can also be used for the cooling mechanism 208. In addition, in such an embodiment, the cooling mechanism 208 can be part of the manifold 242.

10 When a halogen lamp is used as the energy source 202, the change in temperature is so great that air cooling through one or more small, inexpensive fans can be sufficient for the halogen lamp and reflectors of the device. Because generally the surface of the skin is required to be cooled to a much lower temperature, it is still preferable to cool the contact plate 210 (or cooling mechanism 208) with a coolant, such as a chilled fluid or gas. Use of a small fan to cool the lamp reduces the amount of
15 coolant coming into the handheld device 200 from the control unit. This reduces the size of the umbilical cord required to carry coolant and the size and cost of the chiller required to cool the coolant.

During operation, a user applies the device 200 to a subject's skin. The user aligns the contact frame 222 around the precise area of the subject's skin that the user
20 wants to treat. The operator then pushes down (or towards the skin surface) on the handheld device 200, causing the push rods 224 to extend upward within handheld device 200, to bring skin contact plate 210 into contact with the skin surface. When the user presses down or toward the skin on the handheld device 200, the contact plate 210 of the device 200 approaches the contact frame 222 and skin. In other words, as the user
25 presses down on the handheld device 200, the contact frame 222 is pressed against the subject's skin and the push rods 224 move into the housing 300 as the contact plate 210 is forced toward contact frame 222 and skin. When skin contact plate 210 is in contact with the skin surface, push rods 224 activate sensor 226, which indicates such contact to the control unit and/or to the user of the handheld device.

30 Eventually, when the contact frame 222 comes into contact with the contact plate 210, the push rods 224 contact and activate the sensor 226, indicating that the contact plate 210 is in contact with the subject's skin. Because contact plate 210 is cooled,

activation of the sensor 226 indicates that cooling of the skin has begun. The description above describes, and FIGS. 2-15 depict, one embodiment of a sensing mechanism 220. Other sensing mechanisms can also be used within the scope of the invention.

The use of a sensing mechanism 220 aids the user of the handheld device 200.

5 For instance, if the user desires to cool the subject's skin prior to application of radiation, the sensing mechanism 220 aids the user of the handheld device in determining when the cooling mechanism 208 of the device 200 is in contact with the subject's skin. This prevents the user from accidentally believing that the cooling plate 210 is in contact with the subject's skin when it is, in fact, not in contact. Thus, in this
10 embodiment, the sensing mechanism 220 can provide a safety feature for the device 200.

Once the user receives feedback indicating that the contact plate 210 is in contact with the skin, the user may fire the device 200 to irradiate the skin. Where pre-cooling is desired, the feedback from the sensor 226 indicating contact with the skin may be different for a pre-cooling time and may change to indicate to the operator that
15 application of radiation can begin. For example, the feedback may provide a beeping sound while the device 200 is pre-cooling the skin and a continuous tone when it is safe for the user to fire the device 200 to irradiate the skin. In one embodiment, the device 200 may prevent firing by the user until the pre-cooling time is met, and if contact with the skin is broken, the device 200 may start the cycle over. In another embodiment, the
20 firing time of the device 200 is preset such that once the user initiates firing, the device 200 will irradiate the skin for that preset time. In another embodiment, the device 200 will stop the radiation if contact with the skin surface is broken. In another embodiment, the device will provide feedback to the user after irradiation to indicate a post irradiation cooling time.

25 Figure 16 is a flow chart, according to one embodiment of the invention, that illustrates how the device 200 and a control unit can work during operation to aid the user in radiating the subject's skin. The first three steps shown in FIG. 16 can be steps performed by the user. The remainder of the steps, in the embodiment of FIG. 16, can be automatically performed by the device 200 and control unit. In other embodiments,
30 some of the steps can be automated and others can be performed by the user. First, at blocks 1601 and 1602, as set forth above, the user begins the procedure and aligns the contact frame 222 around the target area of the subject's skin. The user next depresses

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the device 200 against the subject's skin (at block 1603) until the sensor 226 indicates that the contact plate 210 contacts the skin in order to cool the skin. At block 1604, the device determines whether the contact plate 210 contacts the skin. When the sensor 226 indicates that the contact plate 210 touches the subject's skin, an indication is sent to the user indicating that such contact exists (at block 1605). If the device 200 or control unit do not provide such an indication, in one embodiment, the user should begin the process again.

In one embodiment, as illustrated in FIG. 16, at block 1606, the control unit and/or handheld device 200 can be configured with a preset cooling time. Such a preset cooling time is an amount of time that the device 200 will wait (or must wait), while the cooling mechanism contacts the subject's skin, before firing of the radiation. Such a preset cooling time can be used as a safety mechanism and/or as a method of automating treatment.

In some embodiments, as illustrated in FIG. 16, at block 1607, the control unit and/or handheld device 200 can be configured with a preset firing time of the energy source 202. Such a preset firing time is an amount of time that the energy source 202 will fire in order to radiate the subject's skin. Alternatively, such a preset firing time can be the number of firing cycles or pulses for the energy source 202 or some combination of the number of firing cycles and length of pulses of the radiation. Such a preset firing time can be used as a safety mechanism and/or as a method of automating treatment. Further, the combination of the use of a preset cooling time and preset firing time can be used to create an automated process. Different preset cooling times and preset firing times can be used for different treatments.

In another embodiment of the invention, as illustrated in FIG. 16, at block 1608, the sensor 226 can determine when contact of the cooling plate 222 with the skin is lost during treatment. As shown at block 1609 in FIG. 16, the control unit and/or handheld device 200 can be provided with an automatic interrupt if the sensor 226 indicates that contact of the contact plate 222 of the cooling mechanism 208 with the subject's skin has been lost. Such an automated interrupt provides a safety mechanism so that the subject's skin is not damaged, for example, by excess heat and/or irradiation. In such an embodiment, if the sensor 226 indicates that contact has been lost, an interrupt signal can shut off the energy source 202. Such an interrupt signal can be generated by the

control unit. In another embodiment, the interrupt signal can be generated on the handheld device 200 so that firing of the energy source 202 is automatically interrupted if contact of the cooling mechanism 208 with the subject's skin is lost. In addition, as shown at block 1610 of FIG. 16, the control unit and/or handheld device 200 can provide
5 an indication to the user that contact has been lost and firing has been interrupted. The user can then restart (block 1611) or abandon the process. In an alternative embodiment, such an automatic interrupt is not used. Instead, in such an embodiment, the control unit or handheld device 200 can indicate to the user that contact of the contact plate 222 with the subject's skin has been lost. In such an embodiment, the use of the device 200 can
10 continue to fire the energy source 202, if desired, after contact of the cooling mechanism 208 with the subject's skin ends.

When a cycle of cooling and firing of radiation has been completed, irradiation of the tissues can end (block 1612) and the cycle can end (block 1613). The control unit and/or handheld device 200 can indicate to the user (through either a visual, audio or
15 tactile signal) that it is safe to reposition the device 200 in order to begin another cycle on a different target area on the subject's skin.

As set forth above, many uses require cooling of the target area of the subject's skin prior to application of radiation. This can effectively protect tissue above the treatment region, can allow for higher fluences and shorter pulse durations, and can
20 insure that the maximum temperature rise in the tissue occurs at or near a desired depth. Pre-cooling is preferable for certain applications, such as the treatment of cellulite, where light or other EMR is applied for a longer period to achieve heating at greater depths. In addition, application of cooling while the radiation is being applied to the subject's skin is necessary or desired for certain applications. Further, post cooling may
25 be preferable in certain applications, for example, to dissipate following applications of light during vein treatments.

The time of radiation application may vary from approximately 2 seconds to approximately 2 hours for depths of approximately 1 mm to 50 mm, respectively. Depending on depth, the treatment being performed, and other factors, the power density
30 may vary from approximately 0.2 to 50 W/cm², more preferably from approximately 0.5 to 20 W/cm², and most preferably from 0.5 to 10 W/cm² or 0.5 to 5 W/cm². The handheld device 200 and/or control unit can have such radiation application times and

power densities preset for different applications, as described above in connection with FIG. 16. In addition, different preset cooling times can be used in connection with different radiation application times and/or power densities.

The graph in FIG. 17 illustrates the relationship between treatment time and
5 depth of heating for light sources operating in the infrared wavelength. Although the depth of heating will be dependent on various factors, including the electromagnetic wavelength used, the type of tissue treated and the power density of the electromagnetic wavelength, FIG. 17 provides a general guideline of the parameters for heating tissue at
10 depth using infrared wavelengths and power densities generally in the range of 0.5-5.0 W/cm². For comparison, the relationship between surface skin temperature (median and standard deviation) and treatment time when pre-cooling is used and the skin is continually cooled during treatment is shown in FIG. 18.

Referring to FIGS. 19 through 23, a handpiece 400 is capable of treating both the dermis and the fat or other tissue beneath the dermis. Alternatively, embodiments of the
15 handpiece could be designed to heat tissue at relatively greater or shallower depths.

To heat tissue more deeply, whether using fractional or conventional methods, the handpiece 400 transmits light to the tissue at a relatively lower level of power for a longer period of time than prior art devices. In other words, the level of irradiance of the tissue is lower, but the power is delivered for a longer pulse width. For example, for
20 some applications, such as collagen stimulation and certain types of pain relief, handpieces and other embodiments can be designed to deliver 10 W/cm² for a period of 1 to 10 seconds. To treat cellulite, however, lower power densities are preferred over a longer pulse width. Therefore, one embodiment of the handpiece 400 is designed to deliver 1-2 W/cm² over the same period of time or longer, that is preferably 0.5s – 600s,
25 although longer periods are possible, depending on depth and extent of treatment.

The following table provides preferable specifications for embodiments designed for several applications, although many other applications are possible.

TABLE 2: Specifications For Various Applications

Application	Skin Remodeling	Acne	Cellulite
Spectrum of Wavelengths	900-1350 nm	900-1850 nm	900-1350 nm
Window Size	12 cm x 28 cm	10 cm x 15 cm	40 cm x 40 cm
Power Density	50 W/cm ²	85 W/cm ²	1-4 W/cm ²
Fluence	5-240 J/cm ²	5-400 J/cm ²	Up to 2500 J/cm ²
Pulse Width	0.25 10 sec	0.25 – 5 sec	0.5 – 600 sec
Skin Cooling Temperature	5° C	5° C	5° C

In an alternate embodiment of the invention, devices such as devices 100 and 200 described above can be used to provide a lower power density by increasing the size of the window through which EMR is transmitted. In other words, rather than decreasing the power density by decreasing the relative amount of power that is produced by the device, the power density can be lowered by enlarging the area of the window that transmits energy to the tissue being treated. In addition to producing a desirable power density, increasing the area has the additional advantage of allowing the handpiece 400 to be used with the same base unit as other handpieces, such as the embodiments described in conjunction with FIGS. 1-15.

Furthermore, handpiece 400 also has the advantage of increasing the area of tissue that is treated at any one time, thereby making treatments faster and more efficient. Thus, the patient is required to spend relatively less time per visit and the person administering the treatment can perform relatively more treatments in the same amount of time.)

With the exception of the alternate window configuration and the inclusion of certain other additional features that are described below, handpiece 400 is essentially the same in function, structure and operation as devices 100 and 200 described above in association with FIGS. 1-16. By way of comparison, however, the devices described above include relatively smaller windows through which EMR passes. For example, referring to FIG. 14, device 200 includes a window 223 that is 12 mm by 28 mm and

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that allows light to be transmitted from lamp 202 (shown in FIGS. 8 and 9) to the tissue being treated. Such a rectangular shaped window can be cooled evenly and thoroughly, e.g., by flushing chilled coolant (generally water) along one or both of the longer 28 mm edges of the window, using the circulatory system discussed above. Such application of chilled coolant causes the heat to be evenly dissipated across the narrow span of the rectangular window.

On the other hand, referring also to FIGS. 19 to 23, the handpiece 400 has a relatively larger window 402 that, in this particular embodiment, is 40mm by 40 mm. The larger window serves to reduce the power density to a level that is particularly suited to treat cellulite by increasing the area of the window relative to smaller windows while still using the same power supply and producing approximately the same amount of irradiance from the light source.

However, due to the large size of the window 402 in handpiece 400, passing fluid along one or more sides of the window is insufficient to dissipate heat from the center of the window, and a relatively hotter area will be created during operation of the handpiece 402, due to the buildup of heat in the center of the window. Therefore, additional features are provided to adequately cool the window, and eliminate any hot spot on the window during operation. In addition to providing cooling along the edges of the window, as in the device 200 and window 223, the window 402 includes two intersecting grooves 404 and 406 that are etched into the upper surface of the window 402. Additionally, window 402 is cooled on all four sides, while the window 223 is cooled only along the two longer sides.

The grooves 404 and 406 extend downward into the window 402 for a distance that is approximately two-thirds of the total thickness of the window. In this embodiment of the window, the grooves 404 and 406 are approximately 4 mm deep while the total thickness of the window 402 is approximately 6 mm, and the grooves are approximately 0.5 mm wide.

The configuration of the grooves 404 and 406 of the window provide sufficient cooling of the central portion of window 402 while obstructing only a minimal amount of light passing through the window during operation of the handpiece 400. First, due to the thin width of the grooves 404 and 406, the grooves 404 and 406 obstruct only a small portion of the window in the direction through which EMR passes. Second, due to

the Total Internal Reflection (TIR) of light within the window against the walls of the grooves 404 and 406 as shown in FIG. 22, almost none of the light 408 or 409 that is incident upon the walls of the grooves 404 and 406 will pass into the grooves, whether the light is traveling from the handpiece or has been reflected back by the tissue. The same is true for light that is reflected or scattered back from the skin during use. The advantageous optical characteristics of the grooves 404 and 406 are due, in part to the relative disparity in the indexes of refraction of the material that forms the window 402 and the index of refraction of water.

Preferably, the grooves 404 and 406 are filled with water during operation. The index of refraction of water (which is approximately 1.33) is lower than the index of refraction of the sapphire window 402 (which is approximately 1.74). Therefore, as will be appreciated by one skilled in the art, light will have a tendency to be reflected by the boundary between the window 402 and the water due to the TIR. Only light that is incident against the boundary at very steep angles will pass through to the water. However, given the orientation of the light source to the window 402, almost all of the light will strike the boundary at an angle that will cause the light to be reflected off the boundary and to continue to pass through the window 402 to the tissue. Thus, only a small fraction of the light will pass into the grooves 404 and 406.

When the handpiece 400 is fully assembled, the upper surface of window 402 abuts a lower surface of a waveguide 403, essentially transforming grooves 406 and 408 into tunnels or capillaries through which cooling fluid can pass. The juncture between the waveguide and the sapphire window 402 preferably includes a dielectric coating that enhances the transmission of light from the waveguide 403 to the window 402 and also serves to seal the junction.

During operation, coolant, preferably chilled water flows from the circulatory system input tube 410 and into the groove circulatory inputs 414 and 416. The water, which has been chilled, preferably to approximately 5° C, flows through the grooves 404 and 406 and along all four sides of the window 402 to cool the window 402. The water passes through an intersection of the grooves 404 and 406 and continues to flow out of the groove circulatory outputs 418 and 420. At that point, the water, which is now relatively hotter due to the transfer of heat from the window 402 to the water, travels

through the output tube and back to the chiller located in the base unit (not shown), where the water is cooled again and pumped back through the circulatory system.

It will be clear to one skilled in the art, however, that the parameters of the handpiece 400 can be altered to optimize the handpiece 400 for other applications. For example, many dimensions and shapes are possible in order to aid in the treatment of the tissue, cooling of the window, and/or for other reasons. Furthermore, a 40mm by 40 mm window or other large size window could be used in a handpiece that produced light at relatively higher power levels to allow the handpiece to be used for treatments that require relatively higher power densities. Treatments such as hair removal that do not require heating tissue as deeply as cellulite and benefit from higher power densities could be performed using a relatively larger window similar to the window 402 of the handpiece 400. Use of such a handpiece would allow for hair removal treatments to be performed more quickly over larger areas of tissue, such as the back or legs. Additionally, the configuration of the grooves could be altered or additional grooves could be added to facilitate cooling of the window or to accommodate an even larger window. Also, hollow cuts, tunnels or capillaries could be created through a window to allow water to flow through the capillaries without having to abut the window against another object, such as a bottom surface of a waveguide, to provide a boundary across the top of a groove to contain the coolant. Additionally, the shape of the groove, cuts, tunnels or capillaries could be cut in various shapes, for example, with a "V" shape, in which the bottom of the "V" extends upwards in order to reduce or eliminate the passage of light through the flat portion of the grooves 404 and 406 that are largely perpendicular to the general direction of the EMR being irradiated. Again, the difference in the indexes of refraction of such a design would allow most of the light incident on the walls of the "V" portion to be reflected. The cuts may have circular, rectangular, triangular or other cross-section. The cuts may be distributed uniformly over the waveguide, thereby eliminating temperature gradients or at least decreasing the gradients from what they would be if only the sides are cooled. The cuts can be parallel or can intersect. The cooling may also be accomplished through evaporation of a liquid like Freon from the cut surfaces.

Similarly, as disclosed, window 402 is a monolithic plate, but it could also be composed of multiple pieces that are affixed together, e.g., glued together. However, in

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such an embodiment, the glue or binding material likely would absorb heat and, thus, decrease the thermal performance of the window. For comparison, referring to FIG. 25, an alternative method of cooling a window from the prior art is shown. A window 502 is cooled by providing a horizontal space 504 between two plates, e.g., sapphire window 502 and a quartz waveguide 506, thereby forming a continuous optical structure to transmit light or other EMR when water is passed through the space 504 to cool the window. However, in such an embodiment, some of the light would be reflected back toward the light source at the interfaces between the water channel and the waveguide and the water channel and the window and the water would absorb some of the energy passing through the window.

Referring to FIGS. 19 and 20, handpiece 400 includes two cooling circuits, each particularly adapted to its purpose. The first cooling circuit cools a contact surface of the handpiece in order to cool the tissue being treated and the second cooling circuit cools the light source. The handpiece 400 is configured to irradiate tissue using near infrared EMR, and it includes a circulatory system to remove heat from the surface of the tissue to be treated and thereby cool the skin and a fan system to cool the infrared lamp. The circulatory system allows chilled fluid, typically water that is chilled to approximately 5° C, to flow from a base unit (not shown), into the handpiece 400 through input tubing 410, around the cooling window 402, and out of the handpiece 400 through output tubing 412. The cooling window 402 can be made of various suitable materials, but is preferably sapphire in the present embodiment.

In the apparatus proposed, skin cooling is implemented through contact with the cooled tip of the sapphire window 402. Several mechanisms for cooling the window 402 are possible. For example, the window should be of a material having good thermal conduction properties, such as sapphire, and cooling fluid can run along one or more of the edges of the window and/or the window can have a plurality of hollow cuts or capillaries extending through the window, with cooling liquid, preferably chilled water, or gas circulating through the cuts, as described above.

The handpiece 400 also includes a second cooling circuit to remove heat generated by light source 422. Light source 422 is a halogen lamp that is designed to operate at a high temperature. The bulb of halogen lamp will be approximately 500° C during operation, and relatively little heat energy must be removed to keep the light

source 422 within operating limits and prevent overheating. Further, because halogen lamps work more efficiently as the temperature increases, removing too much heat from around halogen lamp 400 may reduce the efficiency of the lamp and the performance of handpiece 400. Thus, light source 422 can be cooled with a second circulatory system
5 that does not require an additional cooling mechanism, such as a chiller. Instead, a simpler and less expensive air cooling system can be used.

In similar prior art handpieces, a single cooling circuit is used to cool both the tissue contacting surface and the light source. Using a single cooling circuit means that a compromise must be made between cooling the light source which, as indicated above,
10 runs at a very high temperature, and cooling the skin which is maintained at a much lower temperature to prevent injury. For example, one prior art device compromises by using a single cooling circuit to cool both the light source and skin contact surface to 20°C. Cooling the lamp to 20°C puts a very large burden on the chiller and also does not allow the lamp to run at the more efficient higher temperature. Cooling the skin contact
15 surface and, thus, the skin, to only 20°C limits the amount of light that can be applied to the skin without injury.

Using the first and second cooling circuits as described above eliminates the need for this compromise. The lamp can run at the much higher and more efficient temperature of, for example, 500°C, and be cooled with only a simple, small,
20 inexpensive cooling circuit, such as one or more fans, while the skin contacting surface can be cooled to much lower temperatures, for example, 5°C or lower, allowing more light to be applied to the skin without injury. As a result, the cooling capacity of the water from the chiller located in the base unit is not unnecessarily utilized to cool the lamp. This reduces the burden on the chiller and has the additional advantage of
25 allowing the chiller to be smaller and less expensive or allowing the same size cooler to cool the skin contacting surface to a lower temperature.

Preferably, for devices utilizing halogen lamps, the lamp is coated or otherwise surrounded with a highly reflective material, which increases the efficiency of the lamp. Such an arrangement is disclosed in a U.S. Patent Application entitled "LAMP FOR
30 USE IN A TISSUE TREATMENT DEVICE" filed February 17, 2006 and assigned to Palomar Medical Technologies, Inc.)

In the present embodiment, a fan unit 424 cools the light source, which includes a lamp 422, a reflector 423 and a heatsink 426. Fan unit 424 pumps air into the handpiece 400 and across heatsink 426, which is attached to the top of lamp reflector 428 to allow heat to be transmitted from the reflector to the heatsink. Reflector 428 is preferably coated with gold or other highly reflective metal, such as silver or copper. The heatsink 426 includes fins 430 that dissipate heat to the air, as the air flows around the fins 430 and, subsequently, exits the handpiece 400. The air enters and exits the handpiece 400 via vents 432 and 434 respectively, which are located on opposite ends of the handpiece and are formed as an integrated part of a housing 436 of handpiece 400.

10 In some embodiments, a mask can be used to block portions of the EMR generated by the EMR source from reaching the tissue. The mask can contain a number of holes, lines, or slits, which function to spatially modulate the EMR to create islets of treatment. FIG. 23 illustrates an embodiment in which the islets of treatment are formed generally through the use of a mirror containing openings 452 that are small holes.

15 Referring to FIGS. 20 and 23, the handpiece 400 transfers light to the tissue being treated through the sapphire window 402 located in the face 440 of the handpiece 400. The window 402 is adapted for fractional treatments and, therefore, includes a mask 450 having an array of relatively small circular openings 452, while the remainder of the mask covering the window 402 is opaque and does not pass EMR of other wavelengths during operation. Although the mask may pass some EMR, substantially more will pass through the openings 452. (As discussed below, other embodiments could be adapted for non-fractional applications.) In one embodiment, the mask 450 consists of carbon particles in a film, which is placed in contact with the surface of the skin. The mask 450 is attached to the sapphire window 402, and the mask 450 is positioned between the optical energy source, here lamp 422, and the target tissue when the apparatus is in use. The mask 450 may instead include one or more dielectric layers with a plurality of openings 452 for passage of EMR from the lamp 422 to the target area. Handpiece 400 can, therefore, create treatment islets in the patient's skin. Other embodiments of dermatological devices having similar masks are disclosed in U.S. Patent Application No. 60/561,052, entitled Methods and Products for Producing Lattices of EMR-Treated Islets in Tissues, and Uses Therefore and filed April 1, 2005, which is incorporated herein by reference.

Light passes through the openings 452 in the mirror and strikes the patient's skin, creating islets of treatment. Light reflected by the mirror stays in the optical system through a system of reflectors and may be redirected through the holes to improve efficiency. One effective mask is a contact cooling mask (*i.e.*, it contacts the skin during
5 treatment) with a high reflection and minimum absorption for masking light.

In this aspect, the dielectric layers can have a high reflectance over a spectral band emitted by the lamp 422. The openings in the mask 450 can have various shapes or identical shapes. For instance, the openings can be lines, circles, slits, rectangles, ovals, or irregular shapes. In some aspects, the apparatus can include a cooling or a
10 heating element for cooling or heating the mask during use. The optical energy can be over a wide wavelength band, and, in this case, infrared light is used. The optical energy can be applied with various pulse widths, preferably 100 msec to 1 sec.

Similarly, referring to FIGS. 26, other configurations of the face of the handpiece are possible. For example, the window 470 attached to a waveguide 472 may have
15 spatial non-uniformities. In this case, damage of the skin will be non-uniform. The size of the non-uniform fields may be less than 50 μ m. The non-uniform damage may be useful for skin rejuvenation, or for vascular or pigmented lesions, tattoos, etc., because it decreases the peak of extremely strong damage of the skin: blistering, purpura etc. At the same time, the damaged islands heal quickly because tissue between the damaged
20 islands is not damaged and can therefore provide cell proliferation.

In order to provide non-uniform damage of the skin surface, the window 470 of the waveguide may have a modulated profile 474 as is shown in FIG. 26. A spatial mask 476 may also be coated (reflected mask) on the front surface of the window 470, for example a flat mask having square openings 478 as shown in FIG. 27. Patterned
25 index variations (phase mask) in the waveguide may also be employed. Other optical techniques may also be utilized to accomplish this objective. At least some of the techniques indicated redistribute light to provide selected treatment spots.

Referring again to FIGS 20 and 23, a face 440 of handpiece 400 further includes proximity sensors 442 that are located about the perimeter of the window 402. The
30 sensors can be aligned as shown in FIG. 23, or alternatively, many other embodiments are possible, including placing sensors on each side of a window, on adjacent sides of a

window, at the corners of the window, or in various combinations of these or other configurations. During operation, the sensors 442 ensure that the face of the handpiece 400 is in close proximity to or in contact with the skin or other tissue before the handpiece 400 can be “fired,” i.e., engaged to cause light to be emitted by the lamp 422 and from the handpiece 400. The proximity sensors 442 can be any of a number of appropriate sensors, including pressure sensors, similar in function to the sensor described in conjunction with device 200 that ensure that the handpiece 400 is actually in contact with and pressed against the tissue before the handpiece 400 can be fired.

In the present embodiment, however, electrical field sensors (also known as e-field sensors) are preferred. The e-field sensors 442 detect changes in a low-level electrical field when, e.g., a portion of tissue enters the field. Therefore, the sensor can be used to detect when the tissue is in close proximity to the sensors. Because the sensors are located on the face of the handpiece 400, and about the sapphire window 402, the sensors are able to detect when the tissue is in close proximity to or in contact with the sapphire window 402, and are used to determine when the tissue is in a suitable position for firing the handpiece 400.

Referring to FIGS. 24A and 24B, the e-field sensors can also be used as sensors to determine the type of tissue that is in close proximity to the window 402. The underlying composition of tissue varies based on its location on the body. For example, normal skin tissue 480 has a relatively thicker dermal layer 482 than tissue 484 near the eye, which has a relatively thinner dermal layer 486. Similarly, normal skin tissue 480 has a relatively thicker layer of fat 488 underneath the dermis 482, while the tissue 490 around the eye at similar depths is mostly water. The different compositions of the tissue will affect an electrical field 492 of an e-field sensor differently. The e-field sensors 442 can detect these different effects to differentiate between, e.g., normal skin tissue and tissue located over or near the eye, or to differentiate other types of tissue. The proximity sensors 442, therefore, can be used to provide additional features, such as safety features. For example, if the proximity sensors 442 detect that the face of the handpiece 400 is in close proximity to skin over or near the eye, the controller can cause the handpiece 400 to stop operation or operate with a lower level of irradiance to protect the eye. Similarly, the controller can cause the handpiece 400 to provide various

intensities or wavelengths of light for various tissue types to optimize the treatment being provided.

Alternatively, other sensors could be used to provide contact sensing as well as other features. For example, two electrical contacts could be located in the portion of the handpiece 400 in contact with the skin. When the resistance (or capacitance) measured between the two contact elements was within a range typical for skin, the laser would be enabled to fire. It may also be possible to use a magnetic sensor to detect skin/sapphire contact. Similarly, a capacitive sensor could be used in conjunction with image processing to allow for determination of whether the device is operating on biological skin or some form of other surface. It is possible under proper sampling conditions to extract the type of skin the device is located above. This is accomplished by comparing real time processed images to a stored pattern or calculated set of parameters. In addition, the combination of the capacitive sensor and image pattern recognition, navigation algorithm, and special lotion, can be used to determine the presence of skin hair and provide statistical information about the density and size of the hair.

Handpieces preferably include sensors to make them both eye and skin safe. Many of the applications discussed above require high optical power (~80-500 W), and a reliable contact sensor is typically used to enable the laser to fire only when the optical system (e.g., a sapphire element) is in good contact with the skin. For example, an embodiment of an apparatus to determine contact would include a small illumination source (e.g., diode laser or LED) mounted a few mm away from the window through which EMR passes (e.g., a sapphire element). The laser or diode is preferably located inside the device near the window 402. An illumination source is aimed at the skin surface and may emit at a different wavelength than the high-power light source. A detector having a filter to eliminate light at the treatment wavelength would be located in the handpiece to detect light from the illumination source that has been reflected or scattered from the skin. Thus, when the sapphire is in good contact with the skin surface, scattering and absorption in the skin would attenuate light from the illumination laser. In the case of poor or no skin contact, light from the illumination laser would propagate through the optical system to the detector. Thus, by setting an appropriate threshold, the laser could be configured to fire only when the detector is below a preset level. Note

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that such a detector could also be located in the base unit and an optical fiber used to couple light from the handpiece to the detector.

A second exemplary embodiment of an apparatus for determining optical contact eliminates the use of an illumination source. In this case the detector is configured to
5 detect only light from the treatment source by placing a bandpass filter in front of the detector. This method preferably activates the treatment source in a low-power eye-safe mode until firm contact with the skin is made. Thus, when there is no or poor contact between skin and handpiece, the detector output is relatively low. However, when the optical system (e.g., a sapphire element) is in good contact with the skin, the detector
10 output will be relatively high. Thus, the treatment source would only fire when the detector output was above a preset threshold level.

A simple mechanical sensor could also be used to detect skin/sapphire contact. A spring-loaded pin that was depressed upon contact could be used to enable the laser. Multiple pins located around the perimeter of the sapphire could be used to ensure that
15 the entire sapphire face was in good contact with skin. A commercially available load cell could also be used as a contact sensor.

Typical skin surface temperature is in the 30-32°C, and a temperature sensor could be used to detect skin contact. If the location in which the device was used was with the standard 23-27°C range, the light source could be enabled when the temperature
20 measured by the sensor was within the appropriate range. Alternatively, the laser could be enabled only when the proper temperature versus time slope was measured and disabled when the measured temperature was outside the desired range.

Contact sensor design is described in greater detail in U.S. Application 09/847,043, by Henry Zenzie, filed April 30, 2001, entitled "Contact Detecting Method
25 and Apparatus for an Optical Radiation Handpiece," the substance of which is hereby incorporated by reference.

Referring to FIGS. 19 to 23, handpiece 400 has additional features to assist in the treatment of tissue. For example, the handpiece 400 includes a frame 438 about the window 402. The frame is 50 mm by 50 mm on the outer edge, and has a width of 5
30 mm and a thickness of 8 mm. The frame is made of plastic. The junction between the frame and the face of the handpiece 400 is airtight. In the present embodiment, the

frame 438 is a separate piece that is attached to the face using screws and a sealant. In other embodiments, the frame could be, e.g., formed as an integral part of a handpiece as an injection molded plastic or other material.

5 The handpiece 400 further includes a pump 444, a connection tube 446 and a pressure switch 448.

During the operation of the handpiece 400, the frame 438 is placed against the tissue such that an area of tissue to be treated lies within an area bounded by the frame 438. The pump 444 evacuates air from the volume of space 460 bounded by the window 402, the frame and the tissue through the connection tube. Thus, the pump 444 creates a vacuum, which, in turn, causes the tissue to be pulled into the evacuated space. 10 Preferably the tissue is pulled against the window 402 of the handpiece 400. During operation, the pressure in the space 460 bounded by the tissue, the frame 438 and the window 402 is 15 in Hg and forms a vacuum.

The pressure switch 448 is connected to the pump 444 via a wire. Both are 15 connected to a controller (not shown) in the base unit that receives inputs from pressure switch 448 and controls pump 444 via an umbilical chord that attaches to handpiece 400 at connector 437. During operation, the pressure switch 448 ensures that the skin remains in contact with the handpiece 400 during treatment. Preferably, the area of tissue being treated will remain in contact with the window 402, but may be treated even 20 when not in direct contact with the window 402. If the contact between the tissue and the frame 438 is broken or compromised, air will enter the previously-evacuated space and cause a change in pressure. The pressure switch 448 will sense the change in pressure and send a signal to the controller in the base unit that causes the controller to stop the operation of handpiece 400. When that happens, the handpiece 400 can also 25 provide an alarm to the operator to notify the operator that the contact between the skin and the handpiece 400 has been compromised and/or is not complete. The pressure switch 448 is configured to send a signal indicating that the contact is incomplete. The alarm can be communicated to the operator by one or more of a number of notifications, including without limitation, a flashing light, a sound, or the display of an error code or 30 other information.

The use of suction to pull the area of tissue being treated against (or in close proximity to) the window 402 of the handpiece 400, is thought to have several

advantages, such as the maintenance of good contact between the tissue and the handpiece 400 during treatment. For example, if a handpiece relies on the operator to apply pressure to make contact between the tissue and the handpiece during treatment, the system may allow the operator to treat tissue even when the contact is not optimal, such as when pressure is applied unevenly and/or the entire window 402 of the handpiece 400 is not in complete contact with the tissue during treatment.

The use of suction to provide contact also may have the benefit of increasing blood flow to the skin by distending the tissue, and the blood vessels within the tissue. An increase in blood flow within the tissue being treated will assist in the cooling of the skin at the surface, as the additional blood flowing through the tissue during treatment will provide additional heat capacity, and the blood will carry heat from the tissue as it circulates through the circulatory system of the person being treated.

The handpiece can be further combined to provide for additional types of stimulation intended to enhance the treatment of the tissue. For example, the muscles in the tissue, such as facial muscles, can be stimulated to induce muscle contraction during the treatment. Referring to FIG. 28, in an alternate embodiment of a window assembly 500 that is suitable for use with the handpiece 400. Window assembly 500 includes a frame 502 about a window 504. Window 504 is similar in structure to window 402, having intersecting channels 506 and 508. In this embodiment, window 504 does not have a mask attached or applied, although such a mask could be included in other embodiments. A set of contact sensors 510 are disposed about two opposing sides of the frame 502, while a set of electrical pins 512 are provided along the other two sides of the frame 502. The electrical pins 512 allow for electrical stimulation of the muscle tissue. An electrical current is applied to the tissue via the electrical pins 512, which causes a contraction of the underlying muscles.

Similarly, a piezoelectric motor or a DC motor could be included to provide for vibration of the tissue during treatment. Such additional features are thought to enhance the treatment of the tissue.

While several embodiments of the invention have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and structures for performing the functions and/or obtaining the results and/or

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advantages described herein, and each of such variations or modifications is deemed to be within the scope of the present invention.

For example, those skilled in the art will appreciate that while embodiments have been described in the context of handpieces that can be used interchangeably with a base unit, many other embodiments are possible. For example, a single device could
5 incorporate the base unit and one or more handpieces as a solitary system. Additionally, devices other than handpieces are possible. For example, where applications require longer treatment pulses or longer treatment times to achieve deep heating of tissue, devices that are not required to be held during operation would be advantageous. Thus,
10 a device intended to treat one area of tissue for an extended period could be configured in the form of a pressure cuff or a stationary heating pad that could be laid, taped, clipped, strapped, etc. to the person being treated.

More generally, those skilled in the art would readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be
15 exemplary and that actual parameters, dimensions, materials, and configurations will depend upon specific applications for which the teachings of the present invention are used. Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. The present invention is directed to each individual feature, system,
20 material and/or method described herein. In addition, any combination of two or more such features, systems, materials and/or methods, if such features, systems, materials and/or methods are not mutually inconsistent, is included within the scope of the present invention.

CLAIMS:

1. A dermatological device, comprising:
a light source assembly including a source for generating EMR and a plate for contacting the tissue to be treated, wherein the light source assembly is configured to transmit EMR from the source and through the plate during operation;
a first cooling mechanism for cooling the radiation source; and
a second cooling mechanism for cooling the plate.
2. The dermatological device of claim 1, wherein the first cooling mechanism includes a fan configured to pump air to cool the source.
3. The dermatological device of claim 2, wherein the first cooling system further includes a heatsink in thermal communication with the source, wherein the fan is configured to pump air over the heatsink to remove heat from the heatsink device during operation.
4. The dermatological device of claim 3, wherein the heatsink includes a plurality of cooling fins.
5. The dermatological device of claim 3, wherein heatsink is thermally coupled to the source via a reflector, and wherein the fan is configured to cool the source, the reflector, and the heatsink.
6. The dermatological device of claim 1, further comprising a control unit for controlling the first cooling mechanism.
7. The dermatological device of claim 6, wherein the control unit further comprises a controller in electrical communication with a temperature sensor and in electrical communication with the first cooling mechanism, wherein the controller automatically controls the first cooling mechanism based on information received from the temperature sensor.

8. The dermatological device of claim 1, wherein the second cooling mechanism includes a circulatory system for circulating a coolant.
9. The dermatological device of claim 8, wherein the circulatory system includes a chiller.
10. The dermatological device of claim 8, wherein the circulatory system is configured to cool the cooling surface to approximately at least 5° C.
11. The dermatological device of claim 1, wherein the second cooling mechanism includes a pump, a cooling input, and a cooling output, the cooling input being connected to the cooling surface at an input connection and the cooling output being connected to the cooling surface at an output connection,
wherein the cooling mechanism is configured to supply cooling fluid to the cooling surface during operation via the cooling input and to extract heated coolant from the cooling surface via the cooling output to cool the cooling surface.
12. The dermatological device of claim 11, wherein the second cooling mechanism further includes a chiller.
13. The dermatological device of claim 11, wherein the second cooling mechanism is a circulatory system.
14. The dermatological device of claim 11, wherein the coolant is air.
15. The dermatological device of claim 11, wherein the coolant is a fluid.
16. The dermatological device of claim 1, wherein the second cooling mechanism further comprises a temperature sensor for monitoring the temperature of the tissue.

17. The dermatological device of claim 1, further comprising a control unit for controlling the second cooling mechanism.

18. The dermatological device of claim 17, wherein the control unit further comprises a controller in electrical communication with a temperature sensor and in electrical communication with the pump, wherein the controller is configured to automatically control the pump based on information received from the temperature sensor.

19. The dermatological device of claim 1, wherein the source for generating EMR comprises a halogen lamp.

20. The dermatological device of claim 1, wherein the dermatological device includes at least one additional system component, and wherein the first cooling mechanism is configured to cool the at least one additional system component.

21. The dermatological device of claim 20, wherein the at least one additional electrical component includes at least one of: an electrode, a reflector, an optical element, a heat pipe and a heat exchanger.

22. A window of a dermatological treatment device configured to transmit EMR from a source for generating EMR to tissue being treated, the window comprising:
a pane configured to allow EMR to pass from the dermatological treatment device to the tissue being treated; and
at least one cooling channel extending across a portion of the pane, wherein the area of the channel is substantially less than the area of the pane.

23. The window of claim 22 further comprising:
a frame extending about the pane to secure the pane in the dermatological treatment device;
a first cooling input in fluid communication with a first end of the first channel;
a first cooling output in fluid communication with a second end of the first channel; and

wherein the window is configured to be cooled during operation by fluid traveling through the cooling input, through the first channel and out the second end of the first channel.

24. The window of claim 22, wherein the at least one channel is a groove having an open portion extending along a surface of the pane, and wherein the window further includes an optical surface abutting the surface of the pane such that the groove is enclosed during operation to allow fluid to flow through the channel and to prevent the fluid from flowing out of the open portion.

25. The window of claim 22, wherein the window further includes an optical material between the pane and the optical surface, wherein the material allows some EMR to pass from the dermatological treatment device to the tissue being treated.

26. The window of claim 25, wherein the material is a dielectric coating.

27. A dermatological treatment device for treating tissue located at a depth of at least approximately 0.5 mm, comprising:

a housing containing an EMR source and a window configured to transmit EMR from the source to the tissue being treated;

wherein said power source is configured to produce at least 500 W and the window has an area sufficiently large to produce a power density of less than 5 W/cm².

28. The dermatological treatment device of claim 27, wherein the pulse width of the power source is greater than or equal to 0.5 seconds.

29. The dermatological treatment device of claim 27, wherein the pulse width of the power source is between 0.5 seconds and 600s inclusive.

30. The dermatological treatment device of claim 27, wherein the EMR source is configured to produce at least 1000W.

31. A dermatological treatment device configured to transmit EMR to tissue being treated, the device comprising:

a housing containing a source configured to emit EMR and a treatment window configured to pass EMR emitted by said source to said tissue;

wherein said window has a tissue contact surface area that is greater than 600 cm².

32. The dermatological treatment device of claim 31, wherein the window includes:

a pane configured to allow EMR to pass from the dermatological treatment device to the tissue being treated, at least one cooling channel extending across a portion of the pane, wherein the area of the channel is substantially less than the area of the pane.

33. A window of a dermatological treatment device configured to transmit EMR from a source for generating EMR to tissue being treated, the window comprising:

a pane configured to allow EMR to pass from the dermatological treatment device to the tissue being treated; and at least one cooling channel extending across a portion of the pane, wherein the area of the channel is substantially less than the area of the pane.

34. An apparatus for performing a treatment on tissue, comprising:

a housing having a cooling plate that defines a target treatment area on the tissue when located in proximity to the tissue;

a radiation source for generating EMR, wherein the EMR passes through the cooling plate when irradiated; and

an e-field sensor to indicate when the cooling plate is in proximity to the tissue.

35. The apparatus of claim 34, wherein activation of the sensor indicates that the cooling plate contacts the tissue.

36. The apparatus of claim 34, wherein the sensor is one of an e-field sensor, a capacitive sensor, a resistive sensor, a pressure sensor, and an H-field sensor.

37. The apparatus of claim 34 wherein the sensor is configured to detect changes in an electrical field.

38. The apparatus of claim 37 wherein the sensor is in electrical communication with a controller; wherein the controller is configured to provide signals in response to information obtained from the sensor; the controller is configured to issue a first signal corresponding to the detection by the sensor that no tissue is in close proximity and a second signal corresponding to the detection by the sensor that a first tissue is in close proximity.

39. The apparatus of claim 38 wherein the controller is configured to issue a third signal corresponding to the detection by the sensor that a second tissue is in close proximity to the sensor.

40. The apparatus of claim 39 wherein the controller is configured to distinguish between tissue types based on the input from the sensor, the controller configured to command a first action in response to the detection of the first tissue type and is configured to command a second action in response to the detection of the second tissue type.

41. The apparatus of claim 40 wherein the first action is to treat the tissue and wherein the second action is to not treat the tissue.

42. The apparatus of claim 34, wherein the sensor is mounted on the housing.

43. The apparatus of claim 34, further comprising an output device operably connected to the sensor.

44. The apparatus of claim 34, further comprising a feedback mechanism operably connected to the sensor.

45. The apparatus of claim 44, wherein the feedback mechanism prevents firing of the radiation source until after a predetermined cooling time has elapsed.

46. The apparatus of claim 34, further comprising a control unit to implement a preset cooling time before allowing firing of the radiation source.

47. An apparatus for performing a treatment on tissue, comprising:
a housing having a means for cooling the tissue, wherein the means for cooling includes a surface that defines a target treatment area on the tissue when located in proximity to the tissue;
means for generating EMR, wherein the EMR passes through the surface during irradiation; and
means for sensing tissue in an electrical field.

48. The apparatus of claim 47, wherein the means for sensing activates when the means for cooling contacts the contact frame.

49. The apparatus of claim 47, wherein activation of the means for sensing indicates that the means for cooling contacts the tissue.

50. An apparatus for performing a treatment on tissue, comprising:
a housing having a cooling plate that defines a target treatment area on the tissue when located in proximity to the tissue;
a radiation source for generating EMR, wherein the EMR passes through the cooling plate when irradiated;
a contact sensor to indicate when the cooling plate is in proximity to the tissue;
and
a contact frame operably coupled to the housing, wherein the contact frame is movable from an extended position to a position in which it is in contact with the cooling plate.

51. The apparatus of claim 50, wherein the sensor activates when the cooling plate is in proximity to the contact frame.

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52. The apparatus of claim 50, wherein the contact frame has an interior portion that is open to allow passage of EMR.
53. The apparatus of claim 50, further comprising a push rod connected to the contact frame.
54. The apparatus of claim 50, wherein the push rod is operably coupled to the sensor and wherein the push rod activates the sensor when the cooling plate contacts the contact frame.

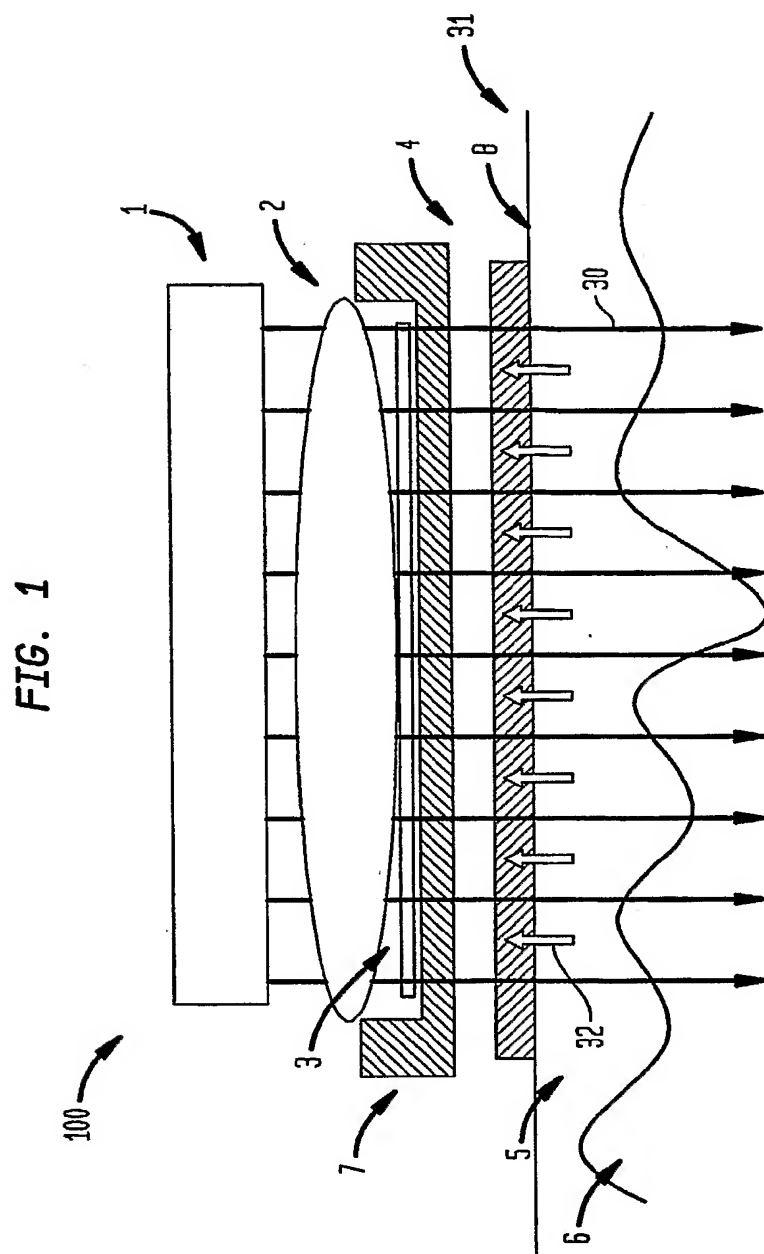
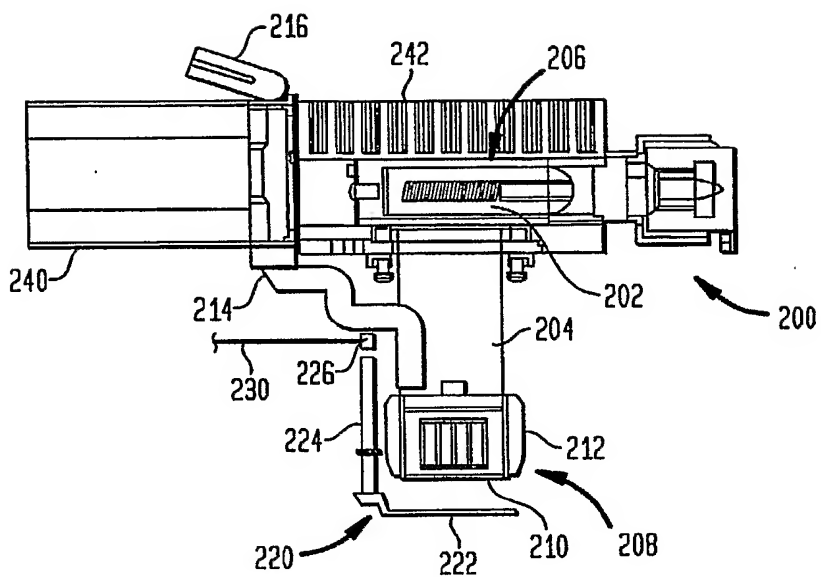
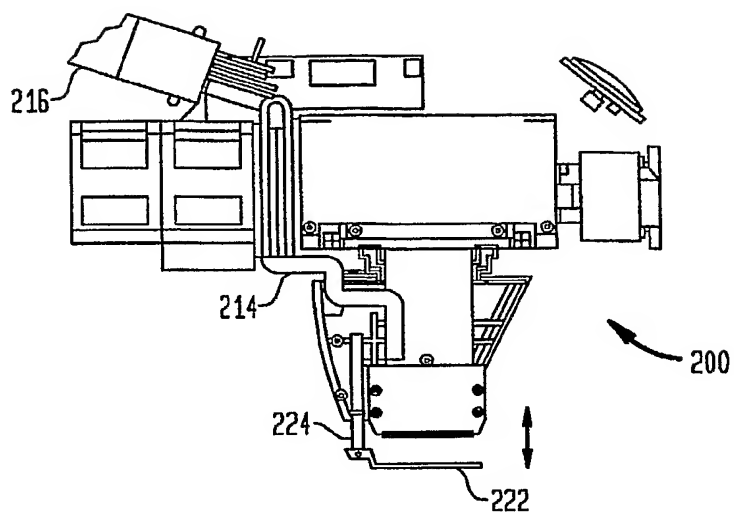
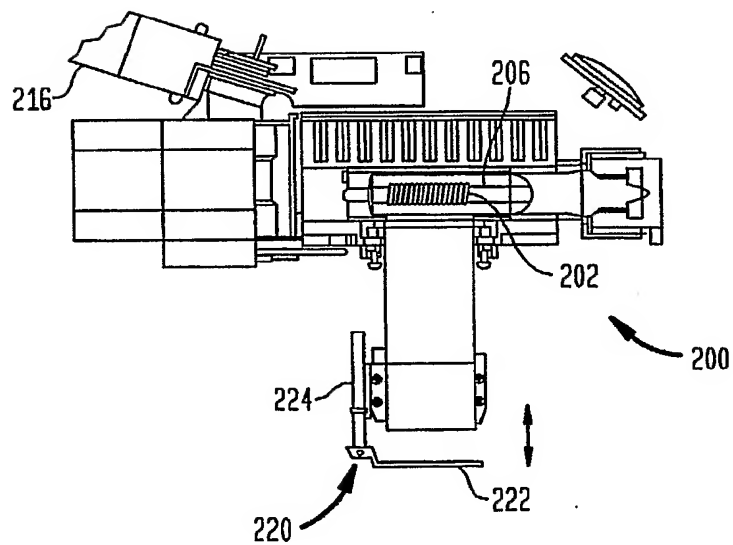


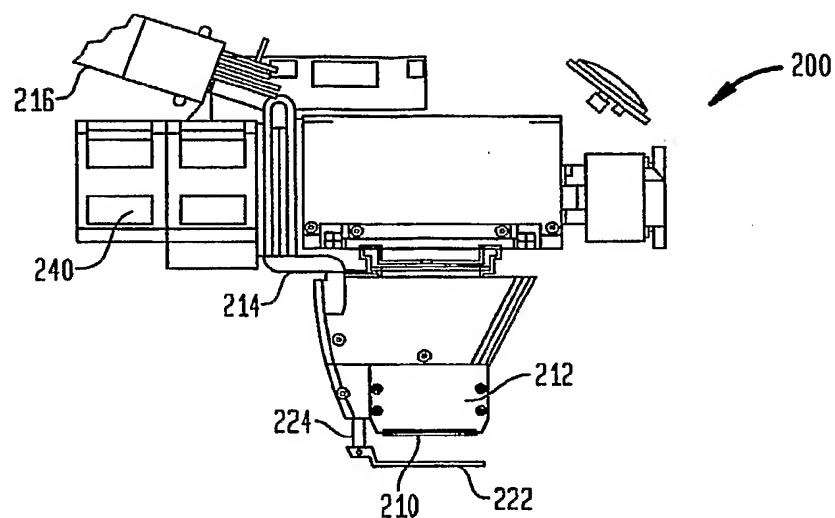
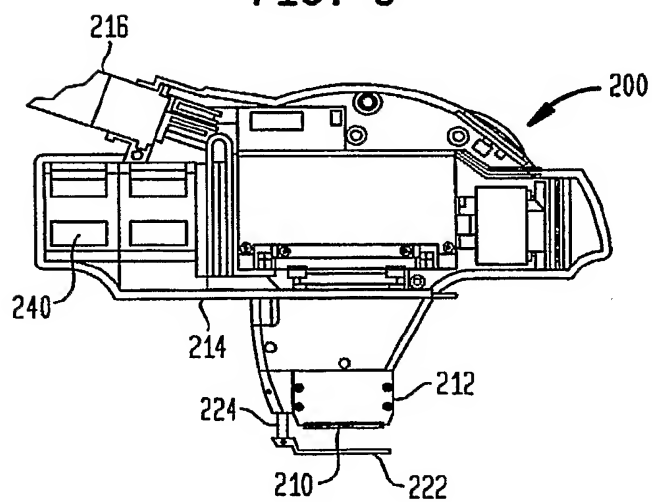
FIG. 2



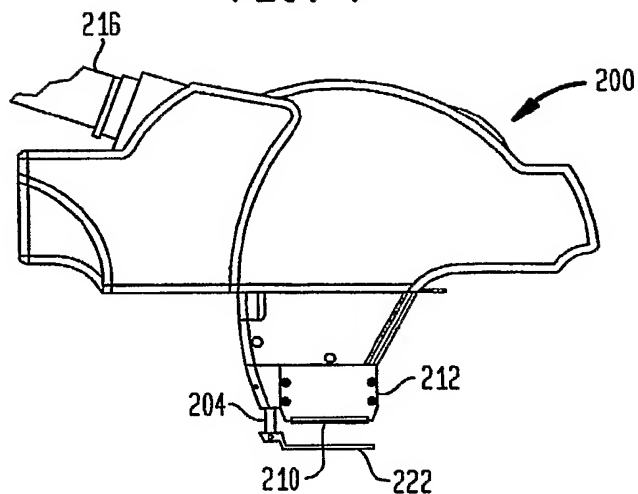
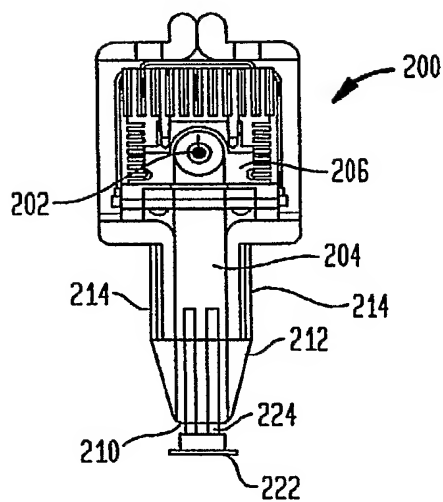
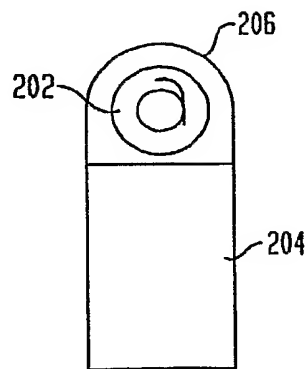
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FIG. 3**FIG. 4**

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FIG. 5**FIG. 6**

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FIG. 7**FIG. 8****FIG. 9**

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FIG. 10

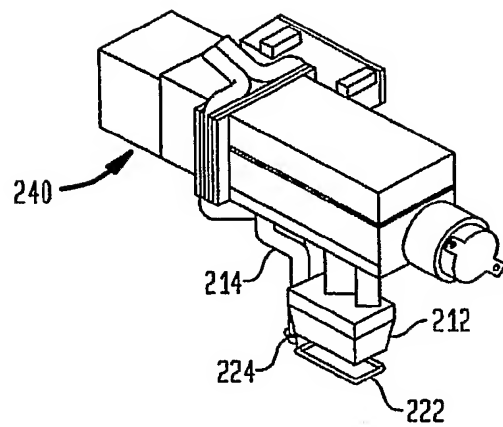
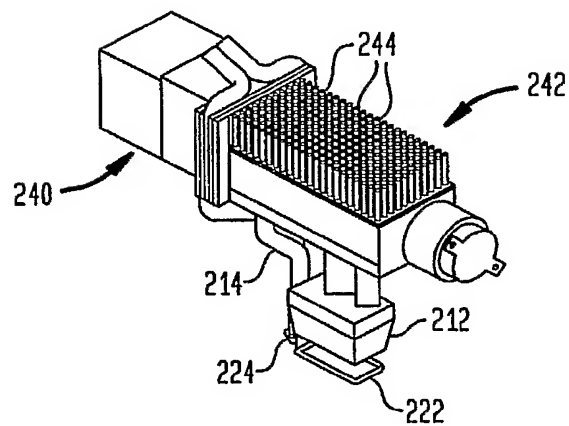


FIG. 11



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FIG. 12

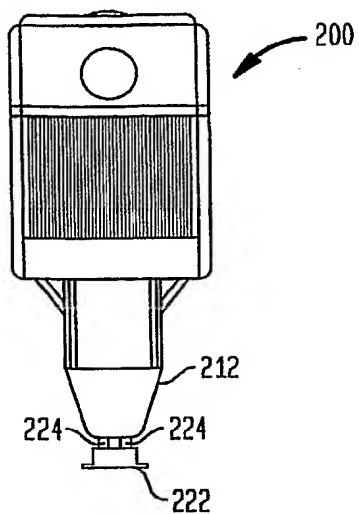
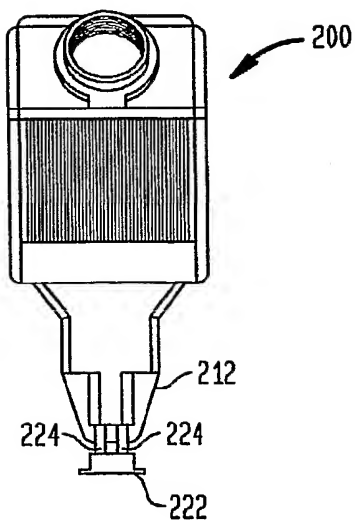


FIG. 13



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FIG. 14

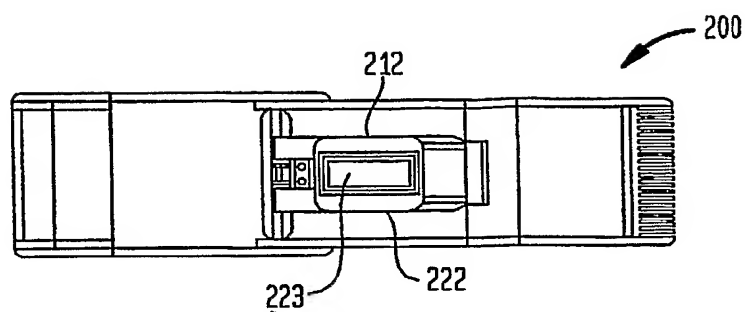
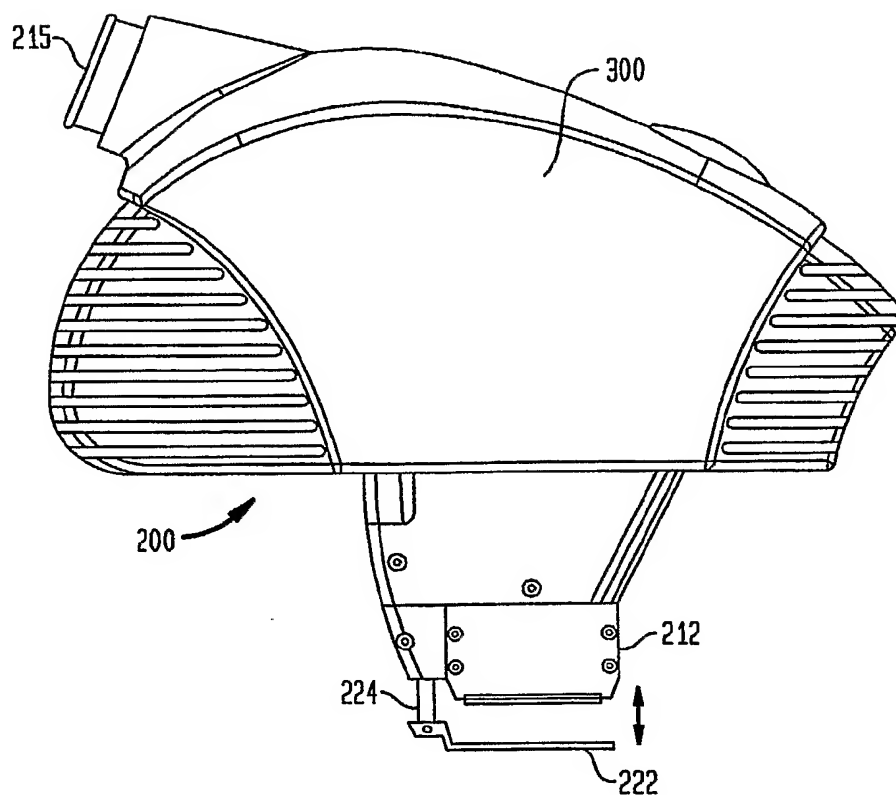
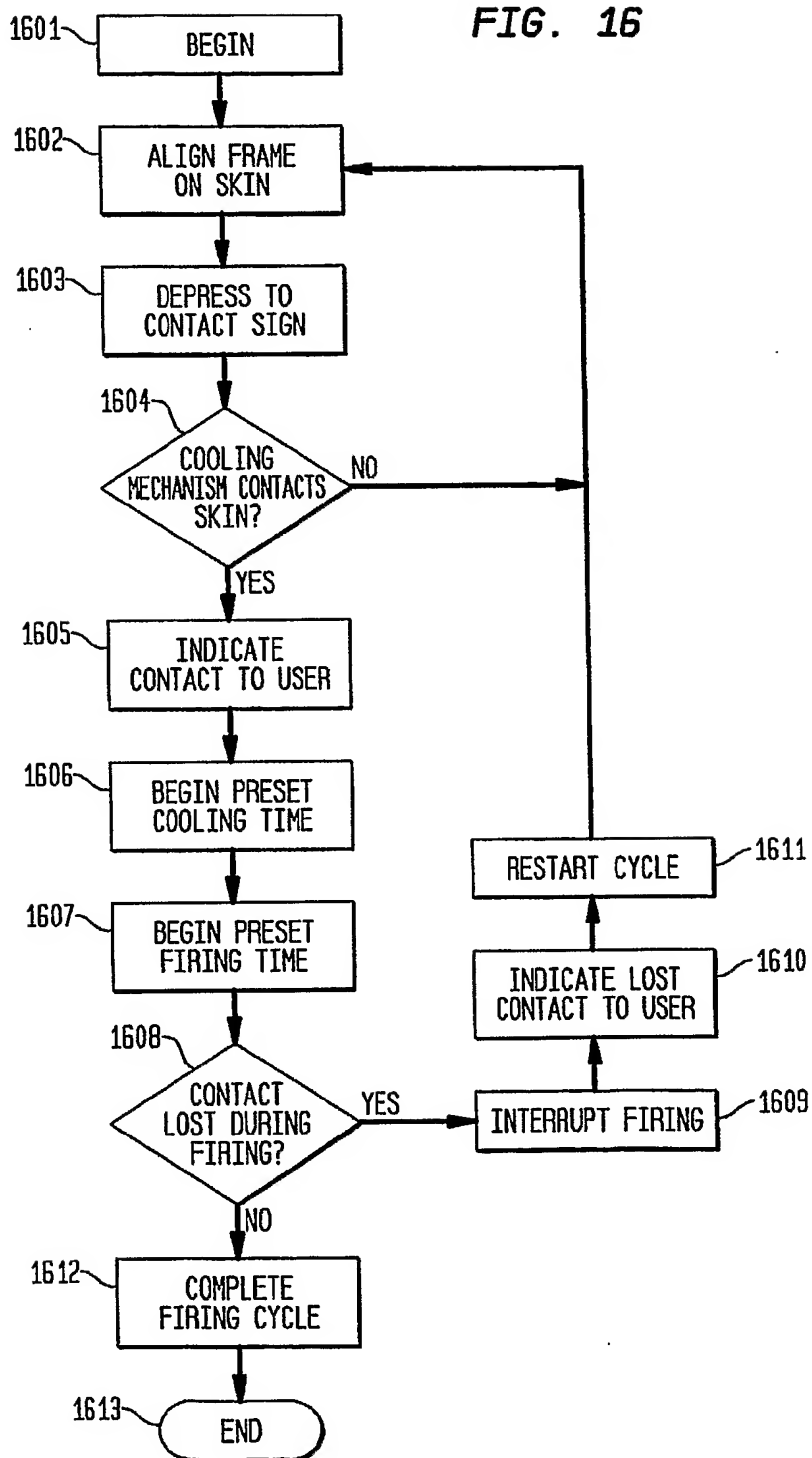


FIG. 15

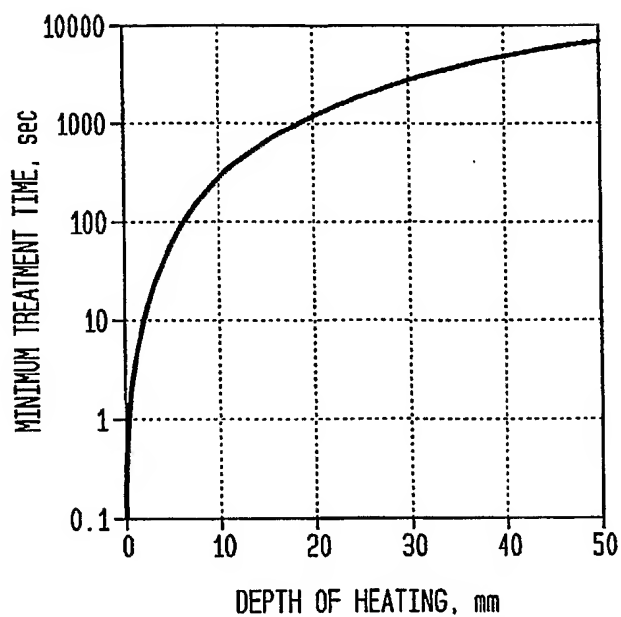
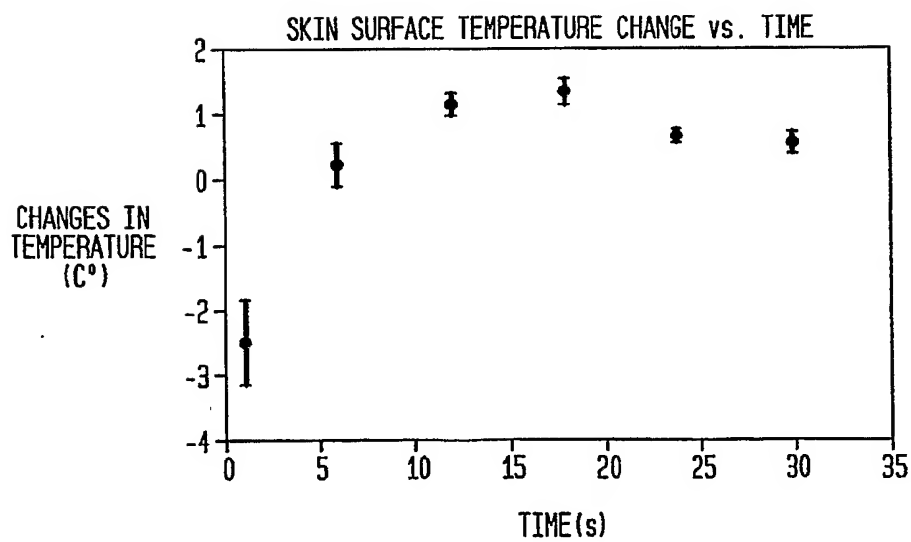


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FIG. 16

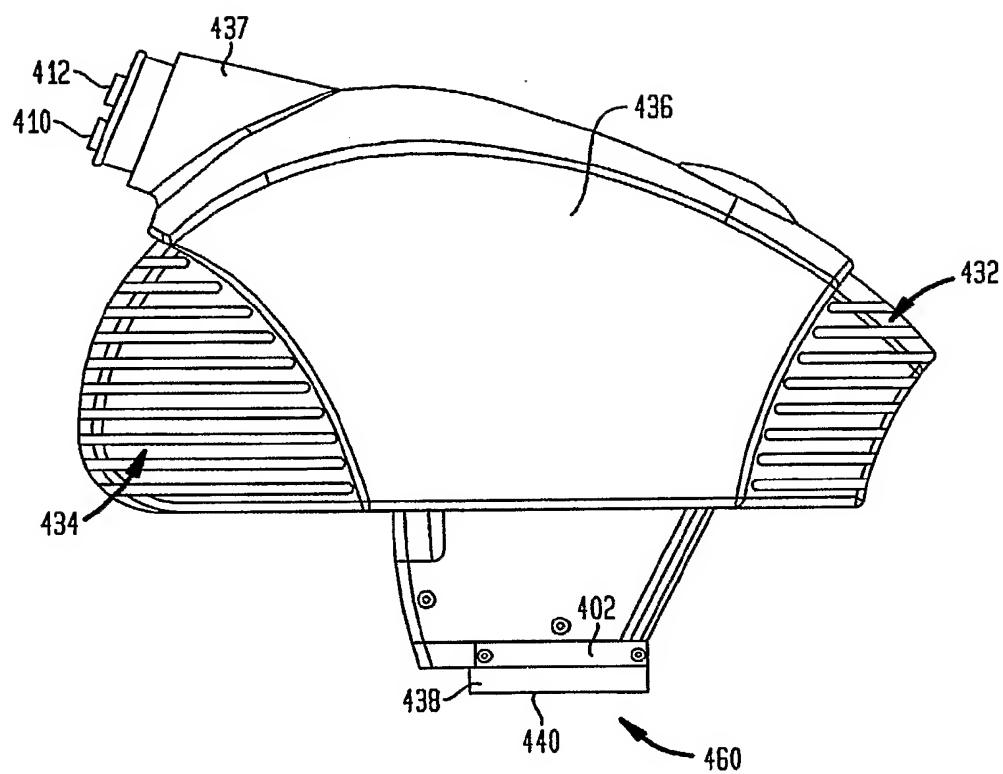


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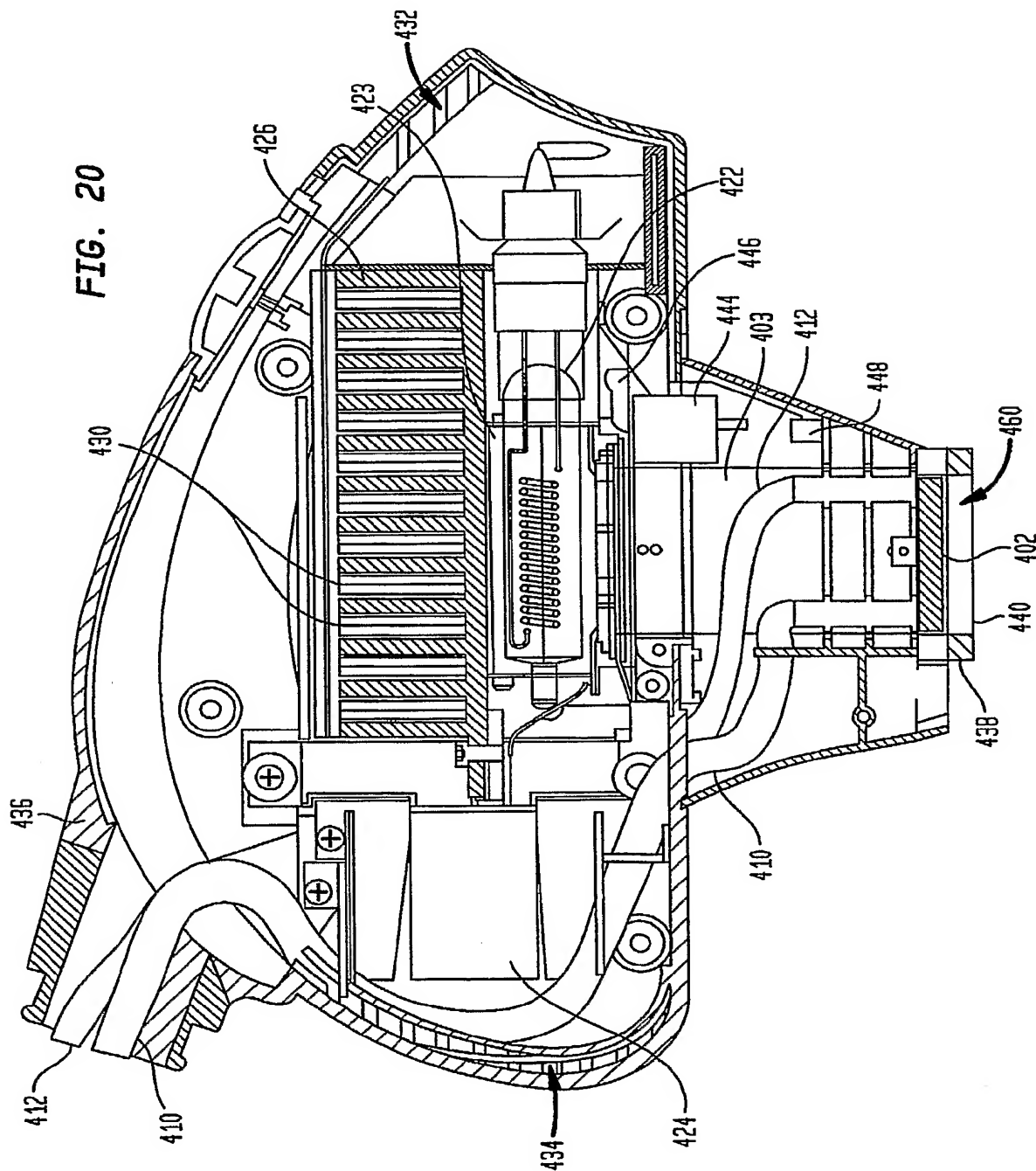
FIG. 17**FIG. 18**

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FIG. 19



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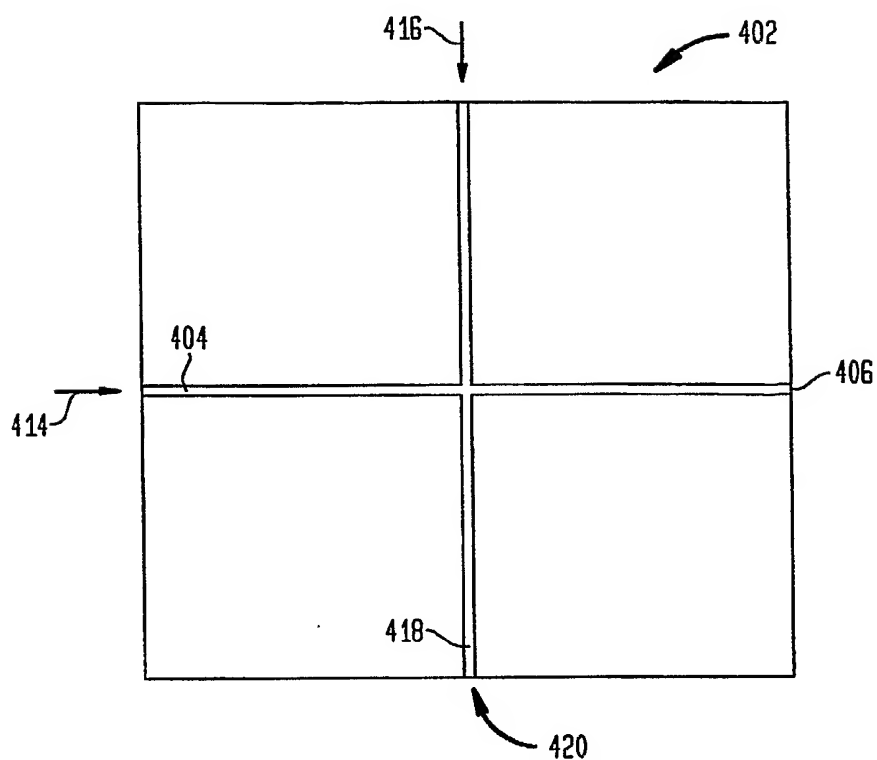
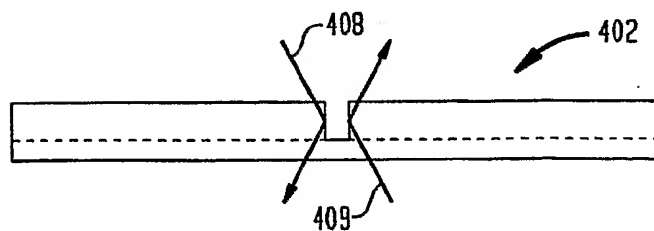
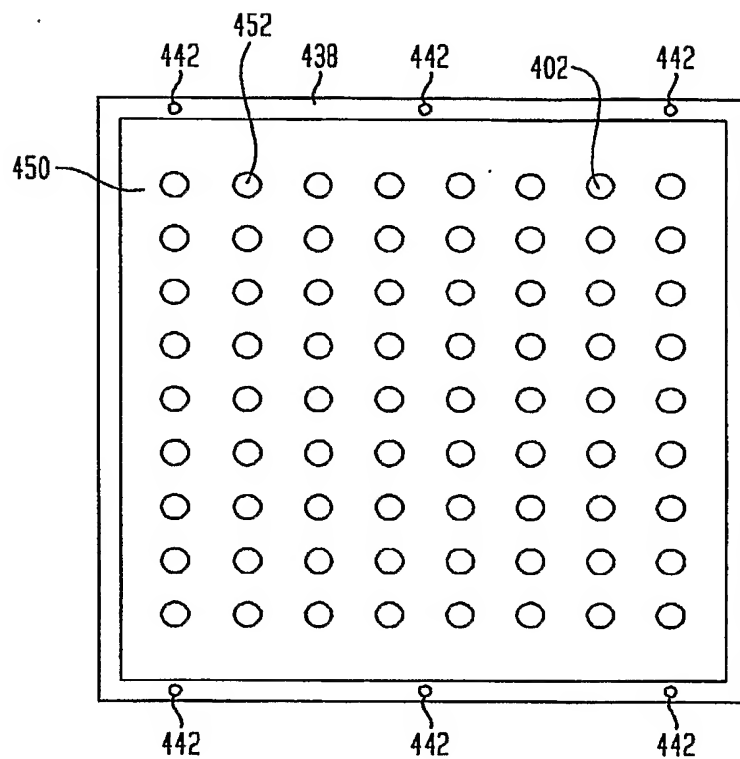
FIG. 21**FIG. 22**

FIG. 23440

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FIG. 24A

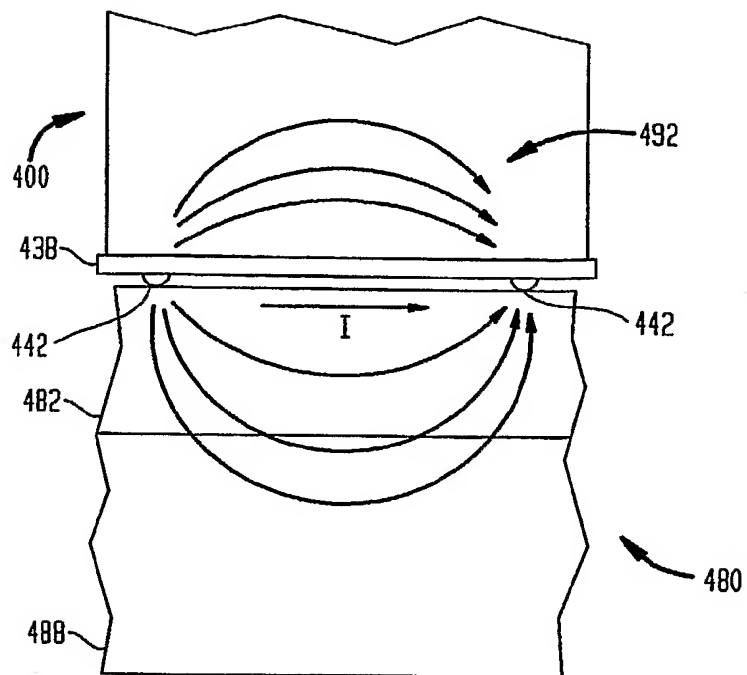


FIG. 24B

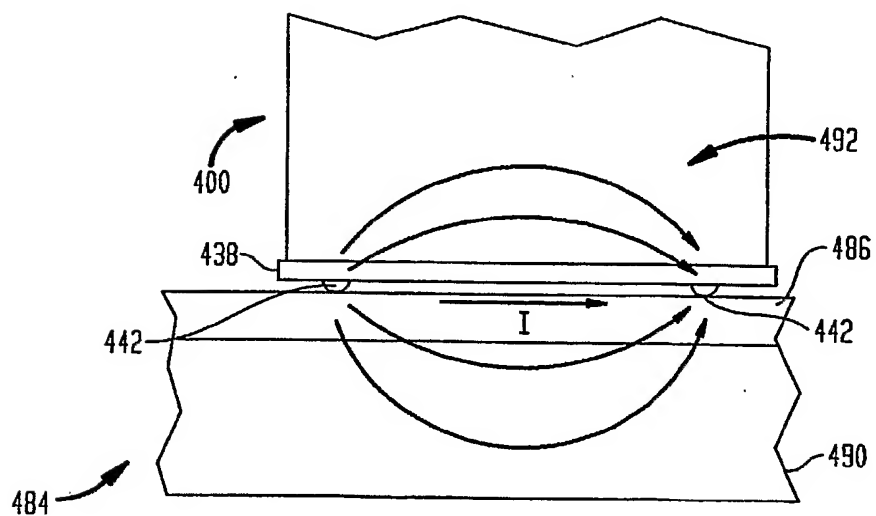


FIG. 25

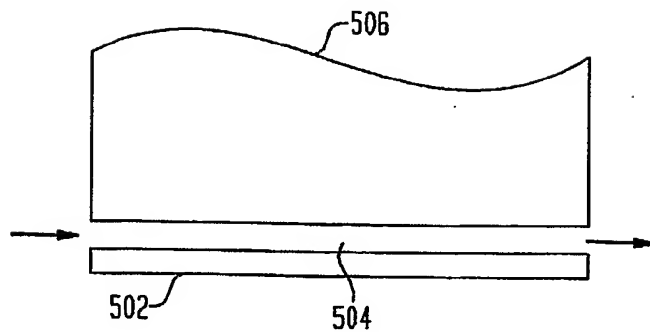
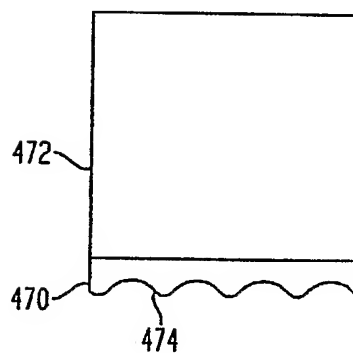
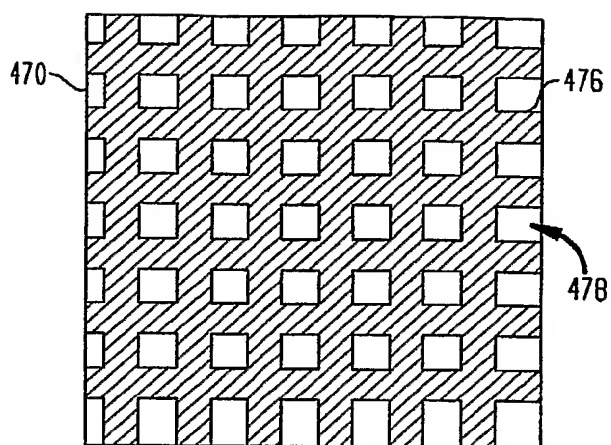
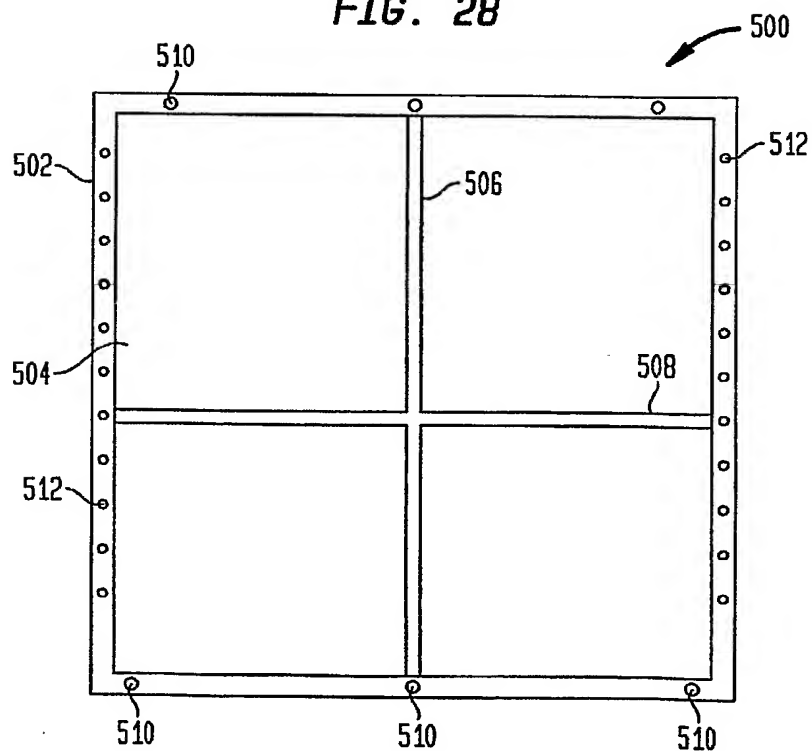


FIG. 26



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FIG. 27**FIG. 28**

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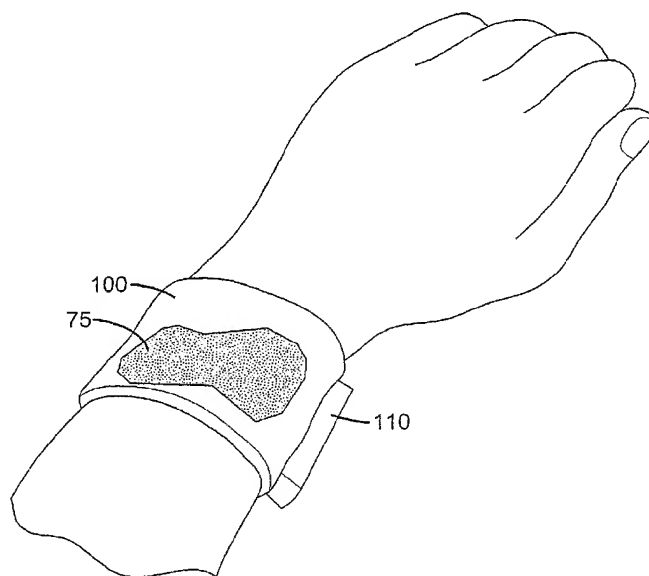
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[Continued on next page]

(54) Title: LIGHT THERAPY DEVICE



(57) Abstract: A light therapy device (40) for delivering light energy to a portion of a patient's body comprises a light source (115). The light source comprises one or more light emitters (122) for providing input light. A light coupling means (80) directs the input light into a light guide (140). A flexible optically transparent light guide material comprises the light guide. A light extraction means (75) is applied to a surface of the light guide material. The light extraction means is positioned to provide light therapy treatment to one or more localized areas of the patient's body. A control means controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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LIGHT THERAPY DEVICE**FIELD OF THE INVENTION**

The invention relates generally to a light therapy device and in particular, to a light therapy device for use in close proximity, or in contact with,
5 the skin or a patient.

BACKGROUND OF THE INVENTION

The term "phototherapy" relates to the therapeutic use of light, and the term "illuminator" or "light therapy device" or "phototherapy device" refers to a device that is generally intended to be used externally to administer light to the
10 skin of a patient for therapeutic purposes.

External light therapy has been shown to be effective in treating various medical conditions, for example, seasonal affective disorder, psoriasis, acne, and hyperbilirubinemia common in newborn infants. Light therapy has also been employed for the treatment of wounds, burns, and other skin surface (or near
15 skin surface) ailments. As one well-known example, light therapy can be used to modify biological rhythms in humans, such as circadian (daily) cycles that affect a variety of physiologic, cognitive, and behavioral functions. Light therapy has also been used for other biological treatments that are less recognized. For example, in the late 1800's, Dr. Niels Finsen found that exposure to ultraviolet radiation
20 aggravated smallpox lesions. Thus, he illuminated his patients with light with the UV filtered out. Dr. Finsen further discovered that exposure with the residual red light sped healing in recovering smallpox victims. Finsen also determined that ultraviolet radiation could be used to heal tuberculosis lesions. As a result, in 1903, Dr. Finsen was awarded a Nobel Prize for his use of red light therapy to
25 successfully treat smallpox and tuberculosis.

In the 1960's and 1970's researchers in Eastern Europe undertook the initial studies that launched modern light therapy. One such pioneer was Endre Mester (Semmelweis Hospital, Budapest, Hungary), who in 1966, published the first scientific report on the stimulatory effects of non-thermal ruby
30 laser light (694 nm) exposure on the skin of rats. Professor Mester found that a specific range of exposure conditions stimulated cell growth and wound healing, while lesser doses were ineffective and larger doses were inhibitory. In the late

1960's, Professor Mester reported the use of laser light to treat non-healing wounds and ulcers in diabetic patients. Mester's 70% success rate in treating these wounds lead to the development of the science of what he called "laser biostimulation."

5 Photodynamic therapy (PDT) is one specific well-known example of light therapy, in which cancerous conditions are treated by a combination of a chemical photo-sensitizer and light. Typically in this instance, several days before the light treatment, a patient is given the chemical sensitizer, which generally accumulates in the cancerous cells. Once the sensitizer concentrations in the
10 adjacent non-cancerous cells falls below certain threshold levels, the tumor can be treated by light exposure to destroy the cancer while leaving the non-cancerous cells intact.

 As compared to PDT, light therapy, as exemplified by Professor Mester's pioneering work, involves a therapeutic light treatment that provides a
15 direct benefit without the use of enabling external photo-chemicals. Presently, there are over 30 companies world wide that are offering light therapy devices for a variety of treatment applications. These devices vary considerably, with a range of wavelengths, power levels, modulation frequencies, and design features being available. In many instances, the exposure device is a handheld probe, comprising
20 multitude light emitters; that can be directed at the patient during treatment. The light emitters, which typically are laser diodes, light emitting diodes (LEDs), or combinations thereof, usually provide light in the red-IR (~600-1200 nm) spectrum, because the tissue penetration is best at those wavelengths. In general, both laser light and incoherent (LED) light seem to provide therapeutic benefit,
25 although some have suggested that lasers may be more efficacious. Light therapy is recognized by a variety of terms, including low-level-laser therapy (LLLT), low-energy-photon therapy (LEPT), and low-intensity-light therapy (LILT). Despite the emphasis on "low" in the naming, in actuality, many of the products marketed today output relatively high power levels, of up to 1-2 optical watts.
30 Companies that presently offer light therapy devices include Thor Laser (United Kingdom), Omega Laser Systems (United Kingdom), MedX Health (Canada), Quantum Devices (United States) and Lumen Photon Therapy (United States).

Many different examples of light therapy and PDT devices are known in the patent art. Early examples include U.S. Patent No. 4,316,467 (Muckerheide) and U.S. Patent No. 4,672,969 (Dew). The most common device design, which comprises a hand held probe, comprising at least one light emitter, but typically dozens (or even 100) emitters, that is attached to a separate drive controller, is described in numerous patents, including U.S. Patent Nos. 4,930,504 (Diamantapolous et al.); 5,259,380 (Mendes et al.); 5,464,436 (Smith); 5,634,711 (Kennedy et al.); 5,660,461 (Ignatius et al.); 5,766,233 (Thiberg); and 6,238,424 (Thiberg).

One shortcoming of the probe type laser therapy device is that it requires the clinician, or perhaps the patient, to actively apply the laser light to the tissue. Typically, the clinician holds the light therapy probe, aims the light at the tissue, and operates the device according to a treatment protocol. As a result, the laser therapy devices are often designed to emit high light levels, in order to reduce the time a clinician spends treating an individual patient to a few minutes or less, whether the application conditions are optimal or not. Additionally, in many such cases, the patient is required to travel to the clinician's facility to receive the treatment. Because of this inconvenience, patients are typically treated only 1-3 times/week, even if more frequent treatments would be more efficacious.

Certainly, these shortcomings with the handheld probes have been previously identified. For example, Laser Force Therapy (Elizabeth, Colorado) offers a disk-shaped probe (the "Super Nova") that can be strapped onto the patient. While this is a potential improvement, the device does not conform to the shape of the tissue being treated. As an alternate approach, a variety of self-emissive light bandages have been suggested, in which a conformal pad having a light emitting inner surface is strapped directly on the patient. Since the patient can wear the device, perhaps under their clothes for a prolonged period of time, the convenience limitations of the handheld probe may be overcome.

As a first example, U.S. Patent No. 6,569,189 (Augustine et al.) provides a heat therapy bandage that uses IR blackbody radiation generated from electrical resistance in circuit trace within the bandage. In this case, since the emitted light is broadband IR (nominally 3-30 microns), this bandage does not

enable the use of specific illumination optical wavelengths that have been suggested to be optimal for treating various conditions. In particular, the wavelengths provided by this device may not advantageously activate the known photo-acceptor molecules in cells. Moreover, this device does not offer a means
5 to vary the light spectrum in any useful way.

As an example, Omnilight (Albuquerque, New Mexico) offers the Versalight pads, which combine a controller (such as the VL3000) with a pad, where the pads comprise a multitude of discrete LEDs imbedded in a neoprene-covered foam. Bioscan Inc. (Albuquerque, New Mexico) offers a similar suite of
10 products for veterinary applications. In both cases, the products typically comprise a mix of IR and red LED emitters, arranged in a pattern across the pad. These devices are described in U.S. Patent No. 4,646,743 (Parris), which teaches conformal pad light therapy devices in which an array of diodes is imbedded in pliable foam. Several other similar devices are known in the prior art, including:

- 15 • U.S. Patent No. 5,358,503 (Bertwell et al.), which provides a conformal pad utilizing tightly packed LEDs, which is placed in contact with the tissue, so as to provide both light and thermal treatments.
- U.S. Patent Nos. 5,616,140 and 5,989,245 (both to Prescott), which
20 provides a conformal bandage comprising laser diodes and flexible circuitry fabricated within a multi-layer pad.
- U.S. Patent 5,913,883 (Alexander et al.), which provides a conformal therapeutic facial mask comprising a plurality of LEDs held off of the tissue by spacer pads.
- Other prior art patents that provide for conformal light therapy pads with
25 discrete light emitters mounted to a pad substrate include U.S. Patent Nos. 6,187,029 (Shapiro et al.); 6,290,713 (Russell); 6,443,978 (Zharov); and 6,743,249 (Alden).

While these various patents provide designs for conformal light therapy pads, these devices are disadvantaged by their awkward construction,
30 which typically involves mounting some number of rigid discrete diodes (lasers or LEDs) within a conformal pad, accompanied by the required drive circuitry and thermal management means. As a result, these devices are encumbered by some

manufacturing difficulties that affect unit cost, and likely limit the potential that these devices could become ubiquitous, if not disposable.

As an alternate approach, there are a variety of technologies being developed for self emissive devices, such as organic light emitting diodes (OLEDs), polymer light emitting diodes (P-LEDs), and thin film flexible electroluminescent sources (TFELs), which could readily enable volume production. As an example, U.S. Patent No. 6,096,066 (Chen et al.) teaches a flexible LED array on a thin polymer substrate, with addressable control circuitry, slits for perspiration, and the use of LEDs, which could be replaced with OLEDs. Similarly, U.S. Patent Application Publication No. 2004/0111132 (Shenderova) discloses a thin film electroluminescent (TFEL) phototherapy device based on high field electroluminescence (HFEL) or OLED technologies. Certainly, light therapy bandages based on these technologies have several potential advantages, including volume production and customizable temporal and spatial control from the addressing circuitry. However, even in the target display markets (laptop computers, television, etc.) OLED technologies are not yet sufficiently mature to support volume production. Also, while self emissive light bandages will not be encumbered by lifetime issues and the resolution requirements imposed on the display market, such bandage type devices will have their own issues (minimizing toxicity, providing sufficient output power or IR output light) that will likely effect the appearance of such devices in health markets.

Therapeutic light pads have also been developed using woven bundles of optical fibers. Such devices are typically marketed for use in treating jaundice in infants. One example is the Biliblanket Plus, offered by Ohmeda Medical (Baltimore, Maryland), which uses a high intensity halogen lamp, mounted in a controller and light coupled into a fiber bundle. The fiber bundle, nominally comprising 2400 individual optical fibers, is configured into a woven pad, in which the bends in the optical fibers cause local breakdown in total internal reflection, so that light is coupled out of the fiber over the full surface area of the pad. Another company, Respironics (Murrysville, Pennsylvania), offers a similar system, the Wallaby Phototherapy System, for neonatal care of jaundice.

The basic concept for a woven fiber-optic illuminator is described in U.S. Patent No. 4,234,907 (Daniel).

This type of medical light therapy pad, using an illuminator comprising a woven mat of optical fibers, is described in prior art patents U.S. Patent Nos. 5,339,223 (Kremenchugsky et al.) and 5,400,425 (Nicholas et al.), both assigned to Ohmeda Inc. For example, the prior art light therapy device of U.S. Patent No. 5,400,425, shown in Figure 1, comprises a woven fiber-optic pad 10 connected by a fiber-optic cable 12 to a drive unit 14 that houses a source of light. The fiber-optic cable 12 has a protective coating of a plastic material such as vinyl and contains a plurality of individual optical fibers, not shown in Figure 1, which transmit the light from the drive unit 14 to the woven fiber-optic pad 10 for emission toward the infant. A connector 16, affixed to an end of fiber-optic cable 12, positions the cable to receive light energy from a light source (internal to the drive unit 14 and not shown). The light source is typically a quartz halogen lamp, although xenon lamps, tungsten halogen lamps, LEDs, and other light sources can be used. Also within the drive unit 14 are the various electrical components and optical components, the latter including optical filters to obtain the desired wavelength of the light radiation delivered to the fiber-optic cable 12 in the range of about 400 to 550 nanometers. Other filters may filter out infrared and UV radiation spectrums from the light radiation delivered. The drive unit 14 is also shown equipped with a controller 20 and a display 22 mounted on the front panel 24, which may facilitate intensity and frequency modulation of the light. In combination with the drive unit 14, fiber-optic pad 10 comprises a plurality of optical fibers woven so as to emit light energy for phototherapy. U.S. Patent No. 6,494,899 (Griffin et al.), assigned to Respiroics Inc., provides an improved device in which the lamp source can be automatically changed after a lamp failure.

U.S. Patent No. 4,907,132 (Parker) provides an improved woven fiber-optic light therapy device where the pad is designed for improved light efficiency and controlled output. Accordingly, the uniformity of illumination of a pad may be varied by varying the shape of the optical fiber disruptions or bends and/or the spacing between such disruptions or bends as by varying the pattern

and tightness of the weave or by varying the proportion of optical fibers to other material in the weave. U.S. Patent No. 4,907,132 also provides that the fiber-optic pad may have a transparent coating laminated applied to the outer surfaces of the disruptions or bends on one or both sides of each optical fiber layer. The coating is intended to cause changes in the attenuation of light being emitted from the pad. The coating increases the overall optical efficiency of the pad by causing attenuation changes only where the light normally escapes from the disruptions or bends of the woven optical fiber panel. While control of the pattern and tightness of the weave certainly will effect light emission over the pad, such customization likely occurs at the factory, rather than at a clinic or even in the home. The other approach, with the transparent overcoat layers, may lend itself to customization at the treatment facility. However, while the over coat seems to offer effective control of the light output, fiber-optic light emission at the bends is largely controlled by the radius of the bends and the core and cladding refractive indices, and applying a transparent coating onto the cladding may only have a secondary effect on the light emission characteristics.

While such systems may have achieved certain degrees of success in their particular applications, there is yet a need for a low cost flexible light therapy device that can be safely, readily, and comfortably used. In particular, it would be desirable if a clinician could modify the output of a light therapy bandage device to provide light at a desired treatment area, but not elsewhere. As an example, a pressure ulcer is typically a localized wound that affects several square inches of tissue. An overlaying bandage, whether a light therapy device, an alginate based bandage, a hydrocolloid dressing, or some other type of dressing, tend to extend over large areas of the surrounding tissue. While a clinician may want some illumination of the surrounding area, that desired illumination area may still be much smaller than the overall bandage size. Moreover, it would be desirable to allow a clinician to customize the light therapy treatment area to follow the typically irregular shape of the treatment area (a pressure ulcer, a burn, etc.). In particular, it would be desirable if the clinician can customize the light emission area to match the wound area during a given visit to the patient, rather than having to make a return trip. Additionally, it would be

desirable if the customized light therapy treatment device can be readily changed upon subsequent visits to the patient. Finally, it would be desirable if such a light therapy device could be fabricated using high volume manufacturing technologies that are already in place today.

5

SUMMARY OF THE INVENTION

Briefly, according to one aspect of the present invention a light therapy device for delivering light energy to a portion of a patient's body comprises a light source. The light source comprises one or more light emitters for providing input light. A light coupling means directs the input light into a light guide. A flexible optically transparent light guide material comprises the light guide. A light extraction means is applied to a surface of the light guide material. The light extraction means is positioned to provide light therapy treatment to one or more localized areas of the patient's body. A control means controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.

10

These objects are given only by way of illustrative example, and such objects may be exemplary of one or more embodiments of the invention. Other desirable objectives and advantages inherently achieved by the disclosed invention may occur or become apparent to those skilled in the art. The invention is defined by the appended claims.

15

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features, and advantages of the invention will be apparent from the following more particular description of the embodiments of the invention, as illustrated in the accompanying drawings.

25 The elements of the drawings are not necessarily to scale relative to each other.

Figure 1 shows a perspective view of a prior art light therapy device comprising a fiber-optic mat type illuminator and a drive unit.

Figure 2 shows a diagrammatic view of a light therapy device in accordance with the present invention.

30

Figures 3a and 3b show side views of the light therapy device of Figure 2 showing application of a light extraction layer.

Figures 4a, 4b, 4c and 4d show top views of the light guide substrate of the light therapy device of the present invention, with different configurations of light extraction layers.

Figure 5a shows a top view of an alternate embodiment of a portion of the light therapy device of the present invention.

Figure 5b shows a side view of an alternate embodiment of a portion of the light therapy device of the present invention.

Figure 5c shows a perspective view of an alternate embodiment of a portion of the light therapy device of the present invention.

Figure 6a shows a top view of an alternate embodiment of the light therapy device of Figure 2 of the present invention.

Figure 6b shows a side view of the Figure 6a alternate embodiment of the light therapy device of the present invention.

Figure 7 shows a perspective view of a light therapy device of the present invention in position to apply treatment to a limb of a patient.

Figures 8a and 8b show views of alternate configurations for portions of the light therapy device of the present invention.

Figure 9 shows a perspective view of a light therapy device of the present invention in position to apply treatment to the face of a patient.

DETAILED DESCRIPTION OF THE INVENTION

The following is a detailed description of the preferred embodiments of the invention, reference being made to the drawings in which the same reference numerals identify the same elements of structure in each of the several figures.

The present invention provides a flexible light therapy device having a plurality of applications, including but not limited to, the treatment of seasonal affective disorder, psoriasis, acne, diabetic skin ulcers, pressure ulcers, and hyperbilirubinemia common in newborn infants. The present invention delivers light energy by means of a flexible member that can be placed in contact with the skin of a patient. The present invention comprises a light guide bandage, in which light is input coupled into the light guide, trapped within by reflection, and emitted in accordance with a light extraction layer. The light extraction layer

can be custom applied, such that the light is emitted nominally onto the area requiring treatment but not elsewhere over the output face of the bandage. The device is nominally designed to be readily worn by the patient for a prolonged time period, and is potentially disposable thereafter.

5 Figure 2 generally illustrates a diagrammatic view of a first embodiment of a light therapy device 40 in accordance with the present invention. As illustrated in Figure 2, light therapy device 40 comprises a drive unit 14 with an internal light source (not shown), a fiber-optic cable 12 to couple light from the light source into the light therapy pad. The drive unit 14 can be equipped with a
10 display 22 and a controller 20, which facilitates setting of treatment parameters such as light intensity, frequency, wavelength, modulation, and repeat treatment timing. While fiber-optic cable 12 is nominally identified as containing a fiber-optic bundle, other flexible light piping means can be used, such as liquid light pipe or solid dielectric light pipe.

15 The light guide therapy pad 100 depicted in Figure 2 is nominally a transparent optical sheet, wherein light is input coupled at input surface 52. Light is then trapped within the light guide substrate by reflections off of outer surface 58, inner surface 60, side surfaces 54, and end surface 56. A portion of the light trapped within the light guide substrate 50 encounters light extraction layer 75,
20 which re-directs the light, so that it is coupled out of the light guide substrate 50 as therapeutic light 62. Light guide substrate 50 is nominally a non-woven sheet material, such as a flexible transparent elastomeric polymer polyurethane. Other polymers could be used, such as acetate sheets, although the substrate could also be made with a thin optical glass. The light is nominally trapped within the light
25 guide substrate 50 by total internal reflection off of outer surface 58, inner surface 60, and side surfaces 54. End surface 56 will likely utilize a reflective layer as mirror layer 82. This reflective layer could be a dielectric (MgF1, for example) or a metal (aluminum, for example) layer to reflect the incident light back into the light guide substrate 50. More likely a commercial reflectance film, such as 3M
30 Vikuiti enhanced specular reflection film (ESR) would be used, with an intermediate adhesive layer used to attach the film to light guide substrate 50. Light guide therapy pad 100 is nominally a wave-guide, with a thickness T that

supports multi-mode light guiding along its length and across its width. Light extraction layer 75, can for example, be an optical diffuser such as a sheet white matte reflective beads which can be cut to a shape corresponding to the treatment area and then externally applied to the light guide substrate 50.

5 Although to the casual observer, light guide therapy pad 100 of Figure 2 may appear similar to the prior art fiber-optic pad 10 discussed with respect to Figure 1, there are several important differences. Light guide therapy pad (or bandage) 100 is not constructed from a multitude of woven optical fibers, but instead comprises a substrate that is a nominally homogeneous optical sheet
10 material. The distribution of the therapeutic light emerging from the prior art fiber-optic pad 10 largely relies on the optical coupling into the individual optical fibers, the distribution of those optical fibers, and the manner and frequency in which bends are imparted to the optical fibers when they are woven. In the case of the light guide therapy pad 100 of the present invention, the distribution of the
15 therapeutic light 62 emerging from the light guide substrate 50 largely depends on the light coupling at the input surface 52, the use of any beam shaping optics at the input surface, and the properties and dimensions of the light extraction layer 75. These differences will become more apparent during the subsequent descriptions of the present invention.

20 Figures 3a and 3b depict cross sectional views of two basic constructions for the light guide therapy pad 100. In the case of Figure 3a, light guide therapy pad 100 comprises light guide substrate 50, with a light extraction layer 75 mounted on outer surface 58. Light extraction layer 75 is nominally a reflective optical diffuser, such as the white reflective diffusers commonly used in
25 the manufacture of laptop computer displays. An exemplary optical diffuser that might be used for light extraction layer 75 is the LTO series reflective diffuser from Tsujiden Co. Ltd. (Japan). In this case, light that incident into the light guide substrate 50 reflects internally until it encounters the diffusing light extraction layer 75. Most of this incident light then diffusely reflects from the light
30 extraction layer 75, back towards the light guide substrate 50, through the thickness T of the light guide substrate 50, and exits out the inner surface 60 as therapeutic light 62. Of course, some of the diffusely reflected light will be

reflected such that it remains trapped within the light guide substrate 50. After multiple reflections, a portion of that light will again encounter the light extraction layer 75, where it will again be diffusely reflected, and may yet contribute to the therapeutic light 62 emerging from the device. Figure 3a also depicts light guide therapy pad 100 as constructed with an optional optical coupling layer 80 between light extraction layer 75 and substrate 50. This layer could have both refractive index matching properties and adhesive properties to enhance the efficiency and uniformity of the optical diffusion.

Other properties of a light guide therapy pad 100 are depicted in Figure 3a. For example, end surface 56 can be coated with a mirror layer 82 to prevent the light from spilling out the ends of the light guide substrate 50. Side surfaces 54 could also be provided with a mirror layer (such as 3M ESR film) rather than relying on total internal reflection to provide the light trapping. Surfaces 54, 58, and 60 could also be coated with scattered matte beads to provide miniature standoffs; so that other applied layers and materials could be kept from defeating the total internal reflection of the light guide outside the treatment area. Input surface 52 could likewise have a mirror coating, aside from any clear apertures that are provided for the input light to enter the light guide substrate 50. A cover 88 can be provided on the outer surface 58. Cover 88 could be a coating or a sleeve, made of gauze or some other material. It could serve several functions, including to protect the light guide therapy pad 100 from damage and contamination (from pathogens; and optically (to prevent degradation of the reflecting and diffusing properties of the bandage surfaces), or to fasten the therapy bandage to other bandage elements (such as straps), etc. Cover 88 could have multiple properties and functions; for example on the outer edges of outer surface 58, it could comprise one or more Velcro strips for attaching light guide bandage 100 to other bandage elements. Cover 88 could also have localized properties elsewhere relative to outer surface 58, such as for protection of the optical properties of the light guide, etc. Cover 88 could also provide a non-stick surface, so the light guide therapy pad 100 does not catch on clothing the patient may wear over the pad. Prior art patents, such as U.S. Patent Nos. 5,759,570 (Arnold) and 6,528,697 (Knutson et al.) suggest approaches for constructing

composite modular bandages that might be appropriate for the light therapy bandage of the present invention.

Light guide substrate 50 may also have layers and coatings on the inner surface 60. For example, a tissue interface layer 84 can be provided, which could have antibiotic properties or bio-sensing capabilities. For example, tissue interface layer 84 could have topical agents that fight infection (including anti-biotic silver), encourage epithelialization or other tissue healing activities, or amplify the effects of light therapy. In the case of bio-sensing, the bio-sensor features might detect a bio-physical or bio-chemical condition of the treatment area, which can then be used as input to guide further treatments. For example, the biosensors might detect the presence or absence of certain pathogens or enzymes associated with infections, or other enzymes and proteins associated with healing. Light guide bandage 100 could also be equipped with a sensing means that changes color relative to time to indicate the time (or amount of exposure) and thereby indicates an end to a given therapy session. For example, biosensors could be used to look for bio-chemical indications of the effective dosage applied. Alternately, optical sensors could detect the backscattered light as measure of the optical dosage delivered. The end of session control could then be manual or automatic.

Light guide substrate 50 may also have adhesive layers 86 on the inner surface 60, which might help to attach the light guide therapy pad 100 directly onto the tissue, or to other bandage elements. Alternately, adhesive layers 86 could represent other types of attachment means, such as Velcro, which could be used to fasten the light guide therapy pad 100 to other bandage elements. Other cover layers (not shown) could also be provided, to aid in assembly of a composite bandage, incorporating other bandage technologies, such as hydrocolloidal or alginate type dressings, silver based anti-biotic dressings, etc. Obviously, the addition of such dressings should minimally interfere with the use of the light therapy bandage. Also, contact with the patient's body can require disposing device 40 within a hygienic enclosure/sheath/sleeve. That is, it is recognized that there may be applications (e.g., instances of potential infections) wherein it may be desired to reduce the potential spread of germs. As such, it may

be desirable to employ a hygienic sleeve, as known to those skilled in the art (e.g., as used with digital thermometers), for example, a transparent material such as a polymer sheet or bag. The sleeve might then be comprised of an anti-bacterial material. Alternatively, light guide bandage 100 might include an anti-bacterial layer disposed on the surface intended for contact with the patient's skin. The adhesive layer 86 could also be spongy, to provide better comfort for the patient when the light therapy bandage is worn.

An alternate cross-sectional construction of light guide therapy pad 100 is shown in Figure 3b. In this case, a transmissive light extraction layer 75 is provided on the inner surface 60 of light guide substrate 50. Light extraction layer 75 could have a micro-structured optical surface, with micro-prisms, micro-lenses, or other features, which will cause incident light (from internal to light guide substrate 50) to refract, diffract, and/or scatter out of the light guide substrate 50 and emerge as therapeutic light 62. An exemplary light extraction layer could be a brightness enhancement film (BEF) from 3M. Potentially, extraction layer 75 could be formed with micro-structured light extraction features that are directly embossed or patterned into either outer surface 58 or inner surface 60 of the light guide substrate 50. Other complementary layers, such as cover 88, mirror layer 82, adhesive layers 86, and tissue interface layer 84 are shown for completeness.

Ongoing research into light therapy has also suggested that it can be advantageous to illuminate the tissue being treated with polarized light, as compared to non-polarized light. Therefore it may be beneficial to equip the light guide therapy device 100 of the present invention with the ability to polarize light. To exemplify this, the conceptual devices of Figures 3a and 3b are shown to possibly comprise other optical layers 81. For example, other optical layers 81 could comprise a polarizing film or a polarization conversion film, as are used in the display industry to build laptop and television displays. Other optical layers 81 could have other desirable properties; and for example be optical filters or be photo-chemically active, and react (change color) in response to bio-chemically emitted light emerging from the tissue in connection to some ongoing biological process. As such, other optical layers 81 could serve as a diagnostic device, similar to the previously mentioned biosensors. The clinician could be equipped

with light guide substrates lacking such other optical layers 81, and apply them as needed, or the dielectric substrates could be pre-fabricated with such layers, and the clinician could be offered a range of light guides with different properties, and choose accordingly.

5 It should be understood that the cross-sectional views of Figures 3a and 3b are meant to be illustrative of the general concepts, and do not represent the actual relative physical size of the various constituent layers and components. Other figures are intended to be similarly illustrative.

10 Another aspect of light guide therapy pad 100 is depicted in Figures 4a-4c. In particular, these figures illustrate the intention that light extraction layer 75 can be optimized to illuminate a given treatment area or areas, even if they are irregular in shape. In particular, Figure 4b depicts a light guide therapy pad 100 with two light extraction layers 75 disposed on a surface. It is generally preferable to pattern light extraction layer 75 in the general shape of the treatment area, and to illuminate the wounded tissue or an area somewhat larger, rather than to illuminate the tissue over the entire surface area of the light guide therapy pad 100, as there will then be greater efficiency in delivering light to the wounded area. In some cases, depending on the size of the wound and the available bandages, or the type of wound, the light extraction layer 75 could cover
15 nearly the entire surface of light guide therapy pad 100.

20 Considering Figures 4a-4c, a clinician might measure directly, or via a digital camera, the boundary regions of a wound. This data would then be transferred over to a sheet of light extraction layer 75 material, where the pattern of the boundary regions would be generally replicated. Depending on the construction of the light guide therapy pad 100, the location of the patient (in a clinic or hospital, or at home) and the capabilities of the clinician, the pattern transfer to the light extraction layer 75 might happen in situ with the patient, or remotely. For example, in the remote case the digital image data for a wound might be transferred to another location, where the light extraction layer 75 could
25 be printed or cut from a material. The final assembly of the bandage could then occur at that location. If the patterning of the light extraction layer 75, and the attachment thereof to the light guide substrate 50, is a simple process, the
30

customized light guide therapy pad 100 could be completed by the clinician in the field.

Although it may be optimal for a clinician to customize the light extraction layer 75 to the wound area, using a digital camera (for example), it may also be that the practicalities of image capture and transfer, and completion of the bandage 100 may prove too cumbersome for some circumstances. Thus, it should be understood that a clinician could be provided with a set of pre-shaped and pre-sized light extraction layers 75 (for example, with round and/or oval shapes). The clinician could then choose the light extraction layer 75 that most closely resembles the desired treatment area. The clinician could then apply the light extraction layer 75 to light guide substrate by the appropriate methods to complete the bandage preparation. Alternately, a range of bandages 100 could be pre-assembled at the factory, comprising a range of differently shaped and sized light extraction layers 75. The clinician could then select the most appropriate bandage 100 from the selection available. Assuming that the bandage cost is sufficiently low, then the burden of having a selection of pre-fabricated bandages available to one or more clinicians could be manageable.

In the prior discussions, it was assumed that the light therapy device of the present invention would be used by applying a light extraction layer 75 to a surface of the light guide substrate, such as a reflective diffuser on the outer surface 58 or a transmissive micro-structured layer on the inner surface 60, where the shape, size, and position of the light extractor can be optimized relative to the treatment area. However, an alternate construction can be used, as depicted in Figure 5c, in which the light extraction layer 75 covers all or most of a surface of the light guide substrate 58, and in which a mask 95 is applied between the inner surface and the tissue. In this case, mask 95 nominally includes an internal patterned aperture 137 that corresponds to the treatment area, through which the therapeutic light travels. Mask 95 can be light absorptive or light reflective. As shown in Figure 5c, mask 95 has a reflective material 70 applied to the surface facing the light guide substrate. Mask 95 is shown offset from light guide substrate 50 for illustrative purposes, but in general, these two items would be held together in close proximity.

The coupling of the input light into light guide substrate 50 can be accomplished by a variety of means. For example, in Figure 2, a fiber-optic cable 12 is shown, attaching to light guide substrate 50 at the center of input surface 52. In this case, while light trapping within light guide substrate 50 will tend to homogenize the light, there will likely be a "hot spot" (an area of higher intensity) near the center of the light guide substrate 50. As most wound patterned light extraction layers 75 would likely be positioned near the center of the bandage 100, it may be desirable to have an intensity hot spot in the center region of the light guide substrate 50. On the other hand, the light guide substrate 50 can be more uniformly filled with light if need be. For example, in the top view of Figure 5a, fiber-optic cable 12 is a "circle to line converter", with the ensemble of individual optical fibers at the output end of fiber-optic cable 12 distributed over a long linear region. As another example, depicted in the cross sectional view of Figure 5b, light source 115 is a linear light source (extending into the paper), complemented by beam shaping optics 125, which couple the output light into the light guide substrate 50. Light source 115, for example, might be a cold cathode fluorescent lamp (CCFL), a neon type tube lamp, or an elongated tungsten halogen filament lamp. Beam shaping optics 125 could include a reflector and a lens, as well as optical filtering (not shown).

Another embodiment of light guide therapy pad (or bandage) 100 is depicted in Figures 6a-6b. Light therapy device 40 nominally comprises a light source module 110 and light guide substrate 50, whereas bandage 100 includes light guide substrate 50 and perhaps a portion of the light source module 110, depending on how design modularity is accomplished. Light source module 110 nominally comprises light source array 120 and beam shaping optics 125. Mounting means (not shown) would be provided to hold these various components in their proper relationships with respect to each other.

For this device, a light source array 120 is shown, which could comprise 1 to N individual light emitters 122. For example, if a fiber-optic cable 12 were branched into N smaller fiber bundles, then light emitters 122 would represent the output end of these fiber-optic bundles. More likely, the plurality of light emitters 122 represent a series of laser diodes, or light emitting diodes

(LEDs), or combinations thereof. As such, the lasers or LEDs could be discretely packaged semiconductor type devices. Molded-in LEDs on flex circuits could also be used, as is done in the display industry (for example, by Global Lighting Technologies Inc.). Discrete laser diodes and LEDs are available from numerous companies, including Spectra-Physics, Coherent, SuperLum Diodes Ltd. Lumileds, Cree, Osram, or Nichia. The ensemble of laser emitters 122 could also represent a monolithic array, such as a laser diode array (although such an array would not likely extend the full width of the light guide substrate 50). The plurality of light emitters 122 could also be provided by other light source technologies, such as organic LEDs (OLEDs), polymer LEDs (P-LEDs), or thin film electroluminescent (TFEL) emitters.

Considering again Figures 6a-6b, the light emitted from light emitters 122 can be coupled into light guide substrate 50 by beam shaping optics 125, which are shown as comprising lens 127 and optical coupler 130. Lens 127 may represent a single lens, a lens system, or other optical elements with optical power. For example, lens 127 could represent a field lens, such as Fresnel lens. Lens 127 would have a focal length determined by the preferential light distribution sought within light guide 50. For example, lens 127 could have a focal length that would cause light to be focused towards the intersection of the two light guide center lines (CL), or a focal length that would correspond to the far end (end surface 56) of the light guide substrate 50. Lens 127 could also include optical power, for example from a cylinder lens, which would help to couple light into the near end (input surface 52) of light guide substrate 50. Beam shaping optics 125 could also include an optical coupler 130, such as a non-imaging optical light concentrator such as a tapered bar or a compound parabolic concentrator (CPC) for enhancing the efficiency of coupling input light into the light guide substrate 50. Beam shaping optics 125 could also comprise a lenslet array, where there may be a lenslet for a light emitter 122 or for a group of light emitters 122. It should be understood that beam shaping optics could also further comprise other optical elements such as spectral filters and optical polarizers.

The light guide therapy device 40 depicted in Figure 6a-6b represents an alternate embodiment to the device shown in Figure 2 in other ways

than just the configuration of the light source and the means for optical coupling into the substrate 50. Considering again the light therapy device 40 of Figure 2, the drive unit 14 (which includes the light source) is separate and distinct from the light guide bandage 100, with the two joined by fiber-optic cable 12. In order to facilitate ease of use by the clinician and the patient, it would be optimal if the light guide bandage 100 could be disconnected from the drive unit 14. This modularity could be provided numerous ways, but optimally, the fiber-optic cable 12 has an interface connector (not shown). Preferably this connector would be located at the juncture of the fiber-optic cable 12 and the light guide substrate 50, or alternately at some short distance (~ 25 mm, for example) prior to the juncture of the fiber-optic cable 12 and the light guide substrate 50. In that latter case, light guide bandage 100 would be assembled with a short length of fiber-optic cable 12 protruding from it, which would then mate to the longer cable extending from the drive unit 14.

In this context, the light guide therapy device 40 of Figures 6a-b can represent another approach to modularity. Certainly this light therapy device 40 can include a separate drive unit 14, much as depicted in Figure 2. However, as the light therapy device 40 in Figures 6a-6b is designed to be compact, and preferably utilize small light sources such as LEDs, then the drive unit could be incorporated somewhere within light source module 100. For example, the functions of controller 20 could be provided by a small circuit board or a flexible thin film circuit could be included in the assembly for light source array 120. Presumably battery power would also be included. If this assembly is sufficiently small and light, it could be an integral permanent assembly with light guide substrate 50. However, as the goal is to provide a low cost light therapy bandage which is easy for the patient to wear for prolonged periods of time, and which further may have the portion that is in contact with the treatment area replaceable, if not disposable, then the various further concepts for modularity may be utilized. For example, the light therapy bandage 100 could comprise light guide substrate 50 and the various coatings and layers (per Figures 3a-b) and little else. In that case, modularity could be enabled by having the bandage separate from the light source module 110 at the juncture of the light coupling means 130 and the light guide

substrate 50. This has the advantage that light guide substrate 50 is nominally a sheet material which can be readily fabricated. On the other hand, changing the light guide substrate 50 could require a clinician to align the flexible sheet light guide substrate 50 to the light source module 110. Attaining that alignment over the width of the substrate 50, while providing efficient light coupling, could be difficult, particularly in the field.

Alternately, modularity could be provided by having light therapy bandage 100 include both substrate 50 and light coupling means 130. Light coupling means 130 could be fabricated separately, and then adhered or fused to the light guide substrate 50. Alternately, bandage 100 could be partially made using an extrusion process, where light coupling means 130 is formed at the end of substrate 50 as one contiguous piece. Light coupling means 130 would still be part of the beam shaping optics 125, but not part of the light source module 110, as it was originally defined. In this case, the alignment of the bandage 100 to the incident light from the light source module would be significantly easier, because the incoming light beam would still be relatively large, as would the light coupling means 130. This would also likely simplify the design of the mechanical mounting interface structures provided for light source module 110 and bandage 100, as well as improving the robustness of the mechanical design. Certainly other design variations can be considered as means to provide modularity for the light therapy device 40 of the present invention.

It is noted that light guide substrate 50 is shown in the figures as having a constant nominal thickness T over the length and width of the sheet. Alternately, substrate 50 can have a wedged profile, with the thicker end corresponding to input surface 52. If the input end is sufficiently thicker, the potential need for a light coupling means 130 may be obviated. Alternately, providing a wedge in the sheet material towards the input surface 52 may ease the mechanical interface to the optical coupling means 130.

Certainly the light guide therapy device 40 would be designed to be adaptable to facilitate treatment of a variety of conditions. For example, the bandage 100 could have a square form factor, as small as 2.5 in. x 2.5 in., or as large as 10 in. x 10 in., or a rectangular form factor, such as 8 in. x 20 in. The

thickness T of substrate 50 would nominally be ~1-2 mm, although it could be as little as 0.1-0.5 mm, as long as the required flexibility is achieved. It may also be desirable that the light guide substrate 50 be fabricated from a material that is extensible, so that the bandage can be stretched and wrapped (for example around a limb). The clinician may also encounter circumstances where it would be desirable to modify the outward shape of the light guide substrate, as wrapping the bandage, even if flexible and conformal, around some portion of a patient's body, may not be an adequate solution. With respect to this issue, Figure 4d depicts a light guide substrate that has been modified with cut edges 65. Unfortunately, cutting the edges in this manner will likely cause light to leak out the new edge surfaces. Potentially the clinician could stop this light leak by applying a reflective layer, such as the previously mentioned 3M ESR film, to the edges. This could be an awkward activity for the clinician to undertake, particularly in the field. Alternately, an easy to apply reflective material 70, such as a quick curing metal (silver, for example) impregnated epoxy or adhesive could be applied along the edges. Although light guide bandage 100 has been generally depicted in the various figures as comprising a substrate 50 with sharp corners, it should be understood that the devices could be initially fabricated with rounded corners, which might aid comfortable application onto a patient.

The operational wavelength could be variable, depending on the condition being treated. For example, the bandages could emit blue light for treating jaundice in infants. Alternately, the bandages could be designed to emit red light (such as 632 nm or 670 nm) or infra-red light (such as 840 nm), or the combination thereof. Numerous academic studies have demonstrated enhanced healing effects for conditions such as burns, pressure ulcers, and chronic pain, with application of red and/or IR light. This is partially because most human tissue has a transmission window, from ~ 630 nm to ~ 1200 nm where light can penetrate ~3-4 mm into the tissue. Furthermore, various bio-chemicals, such as cytochrome oxidase, have been shown to be particularly photo-reactive to incident light in that spectral range. The energy received by such photo-chemicals can then be used in various ways to enhance healing. Also, as some studies have suggested that laser light may provide more efficacious healing than does

incoherent light (such as that from LEDs), it is emphasized that the light source can comprise one or more lasers (such as laser diodes), which can be used by themselves or in combination with incoherent light sources. It is also noted, that in many of the published light therapy studies, the applied optical intensity ranges
5 between 5-100 mw/cm². The light guide bandage of the present invention is generally intended to meet these apparent optical power needs. However, given that the light guide bandage is intended to stay on a patient for a prolonged duration, then it is intended to employ longer exposure times at lower power levels. The lower power levels do need to fall within a range where reciprocity
10 applies, and lower power levels still provide a beneficial effect, rather than little or no effect. For example, biological time constants or threshold effects may limit the lower level of light exposure.

Controller 20 nominally provides intensity control, as well as light modulation (nominally at frequencies in the 5 Hz – 5 kHz range) and
15 repeat treatment programming capability. Controller 20 could also include intensity calibration functionality, as well as data management for any feedback or bio-sensing capabilities that might be built into the bandage. Depending on the circumstances, it may or may not be desirable to allow the consumer or patient to control the operation of the light therapy bandage of the present invention.
20 It should be understood that the light therapy device of the present invention could be used not only for light therapy, but also for photodynamic therapy (PDT).

To illustrate the general concept of the light therapy device 40 of the present invention, Figure 7 is provided, in which a light guide bandage 100 is
25 shown wrapped around a patients arm. Light guide bandage 100 may also be equipped with apertures 135 (see Figure 8a) to allow the passage of air flow and perspiration, or to allow clearance for appendages (fingers; for example). The inside edges of apertures 135 could be coated with a reflective layer, such as the metallized epoxy that was mentioned previously. Figure 9 then shows a general
30 concept of the light guide bandage 100 as a facial mask attached to a patients head with straps. In this instance, the apertures 135 more readily allow the patient to breathe, talk, see, and smell while wearing the mask. For example, the clinician

could use a digital camera to capture an image of the patients face, then down load the image onto a light guide template, which would determine how the apertures 135 should be shaped and positioned. In this case, light guide bandage 100 may not only be flexible and conformal, but may also be molded to better follow the complex features of the tissue it is applied to. Figure 8b shows another alternative concept where the light guide therapy device 40 is equipped with a light guide adaptor 140 that protrudes from the inner surface 60 of the substrate 50. For example, a light guide adaptor 140 might facilitate treatment in circumstances where there is dense hair, such as a cranial treatment or a veterinary treatment (where there is fur), in which a goal is to avoid shaving the hair off while still allowing treatment.

The conceptual designs for the light therapy device of the present invention have been discussed with emphasis on providing a low cost, customizable, light therapy bandage that is modular. In part, the modularity is emphasized as an enabling means to allow the clinician to adapt the bandage to the changing characteristics of the wound over time. In part also, the emphasis on modularity and low cost is also to enable the clinician to readily change and adapt the bandage in the field. In this latter context, it needs to be understood that a clinician may change normal bandages on a wound 2-3 times per week. Thus the light therapy bandage needs to have sufficient ease of use, as well as a low enough cost, that its use is economically feasible. If the cost of the entire device was sufficiently low, then the entire bandage, light source included, could be discarded after use. But as the light source module 110 or the drive unit 14 will likely have some significant costs associated with them, it is likely desirable to have a modular design, where the light guide bandage can be separated from the light source. Alternately, the light source emitters, can be formed directly onto the substrate 50. For example, either patterned organic LEDS (O-LEDs) or polymer LEDS (P-LEDs) could be fabricated at an edge or side of substrate 50, so that the emitted light is directly coupled into the substrate. Perhaps, the molded-in LEDs on flex circuits, integrated directly on an edge of the substrate 50, could also be used. In such instances, the modularity of light therapy bandage 100 could be compromised in order to have a fully integrated light source and light guide,

provided that the cost of the combination unit was still sufficiently low, that the bandage 100 could be cost effective. The advantage in this case, is that with the light source module 100 effectively integrated into the bandage with a very low profile, the thickness and rigidity of the bandage 100 at the light input might be
5 minimized, potentially making the device usage easier for both the patient and the clinician.

The light therapy bandage 100 of the present invention is generally conceived to have a combination of adaptability, physical flexibility, modularity, and low cost, that a clinician would readily apply it to a patient for an extended
10 period of time (for example, several days), during which the device would likely operate according to some predetermined protocol. For the light therapy bandage of the present invention to have the greatest utility, it should be integrated with other bandage elements. Preferably, bandage 100 could be combined with other types of bandages or dressings, such as hydro-colloidals, alginates, or anti-biotic
15 silver bandages. In such a case, these other bandages or dressings would provide required functions to keep the wound moist and suppress infections, and bandage 100 could slip into a sleeve or pocket in one of the other bandages. Attachment feature 86, which could be an adhesive or Velcro, could be used to assist such combinations. In such instances, it would likely be required that any bandages or
20 dressings that are intervening between bandage 100 and the wounded tissue be sufficiently transparent at the treatment wavelengths, that the treatment light can effectively reach the tissue. Of course, exudates (fluid, cells or other substances that have been slowly exuded, or discharged, from cells or blood vessels) may be present and reduce the effectiveness of the light therapy from the bandage 100.
25 Thus, it is generally preferable that bandage 100 can be cleaned. Therefore, bandage 100 may be combined with other types of dressings, such as vacuum sponges, that help remove exudates. Additionally, bandage 100 may be equipped directly with the previously mentioned tissue interface layers 84 (preferably transparent) that provide the needed features of modern bandages or dressings;
30 such as alginate or anti-bacterial silver functionality. In that case, bandage 100 may include a foam or gel that contacts the tissue. Preferentially, bandage 100 can be cleaned and re-used on the patient. Light guide bandage 100 likely also

needs to be waterproof and crushable, as well as non-allergenic. Some portion of the bandage or dressing including bandage 100 needs to be moisture permeable and breathable. The light source and associated drive electronics could be re-used, perhaps rented or leased, or sold to the clinician or consumer for ongoing
5 use.

It is noted that light guide therapy pad 100 is also generally similar to the light guides used in backlights for laptop computer and mobile phone displays. Display backlighting systems typically comprise a light source, a light guide member, and a light extraction means. For example, the light source is
10 typically a cold cathode fluorescent lamp or an array of LEDs that are coupled into one end of the thin sheet light guide. The light guide substrate can likewise be equipped with a light extraction layer, such as a light diffusion layer, or a prismatic sheet. In many cases, the light extraction means comprises a volume diffusion mechanism, such as beads or bubbles that act as light scatterers, and
15 which are imbedded in the light guide itself. There are numerous prior art patents known in the art for display backlights, including U.S. Patent Nos. 5,005,108 (Pristah et al.); 6,079,838 (Parker et al.) and 6,712,481 (Parker et al.). The most important difference for the present invention, and in particular light guide therapy pad 100, as compared to the prior art known from display backlighting, is that the
20 display backlights designs are motivated to provide uniform spatial and uniform angular light output over nearly the full length and width of the light guide panel. In particular, in the backlight applications, the goal is to reduce the spatial non-uniformity over the display to a few percent, so that the user is nominally unaware of any residual variation within the viewing area. Many backlight display designs
25 employ spatially variant or patterned diffusers, micro-structures, or deformities, but with the goal to transform a non-uniform light input (often at one end) into a spatially uniform light output over nearly the full area of the light guide. Likewise, the goals in backlight design often include control the horizontal and vertical angular directionality of the output light, to maximize light efficiency
30 within the likely viewing angles (for example $\pm 15^\circ$ vertically and $\pm 30^\circ$ horizontally) to allow the user to view the screen with minimal change over some angular range, as for example, the user turns his or her head. The display

backlights, which are usually illuminating a liquid crystal panel, are also usually equipped with other layers, such as color filters (and particularly color filter arrays) and contrast enhancement layers, so that the display provides high contrast full color illumination. As the light guide therapy device of the present invention
5 does not employ addressed modulated high-resolution pixels, neither color registered color filter arrays nor contrast enhancement layers are needed.

The light guide therapy pad 100 of the present invention is different and distinct from the display backlights in several regards. In particular, the light extraction means (light extraction layer 75 or mask 95) of the present
10 invention is not nominally applied to the entire surface area of the light guide, but is only applied to a smaller portion corresponding to one or more treatment areas. Therefore, spatial uniformity of the light distribution exiting the light guide 100 is not a priority, and may not even be desirable (per Figures 4a, 4b). Likewise, the light guide 100 of the present invention is not designed with an emphasis on
15 controlling the angular spread of the exiting light. In general, the design goal would be to have the therapeutic light 62 emerge over some range of angles, from normal existence out to θ_{\max} , where θ_{\max} is likely between 20-45°. However, separate control of angular emissions in the two meridians ("horizontal" and "vertical") is not required. Importantly also, the light guide therapy pad of the
20 present invention is designed to facilitate customization of the light extraction to match the treatment area, as well as to facilitate the potential disposability or reusability of all or a portion of the light guide therapy pad 100. In this context, the pad 100 is designed so that the clinician can apply a light extraction layer 75 or mask 95 to the light guide substrate 50, as well as remove and replace the light
25 guide bandage 100 relative to the light source module 110 or the drive unit 14. In contrast, display backlights are designed as factory integrated packages, with the light source (such as the CCFL) and the light guide held in a fixed relationship, without any intent for user modification. The user is not expected to change the light guide relative to the light source, or to alter the light extraction capabilities of
30 the light guide. Additionally, while the light guide therapy pad 100 of the present invention may be equipped with secondary layers and functions, such as anti-biotic layers, adhesive layers (to the tissue), non-stick layers, or bio-sensing

layers, these layers are functionally different than the color filter and contrast enhancement layers provided in display backlights.

Throughout the previous discussions in which the present invention has been described, the focus has been directed towards the treatment of wounds, such as chronic wounds, as exemplified by pressure ulcers. Certainly the device of the present invention can be used to treat other types of chronic wounds (such as diabetic ulcers or venous stasis ulcers), as well as acute wounds (such as cuts and incisions), burns, jaundice, and various skin conditions (acne, psoriasis, fine lines and wrinkles, etc.), as well as other conditions not listed here. Under the appropriate circumstances, the device of the present invention might even be used for internal (such as body cavity) treatment applications.

PARTS LIST

	10	fiber-optic pad
	12	fiber-optic cable
	14	drive unit
5	16	connector
	20	controller
	22	display
	24	front panel
	40	light therapy device
10	50	light guide substrate
	52	input surface
	54	side surface
	56	end surface
	58	outer surface
15	60	inner surface
	62	therapeutic light
	65	cut edges
	70	reflective material
	75	light extraction layer
20	80	optical coupling layer
	81	other optical layers
	82	mirror layer
	84	tissue interface layer
	86	adhesive layer
25	88	cover
	95	mask
	100	light guide therapy pad
	110	light source module
	115	light source
30	120	light source array
	122	light emitters
	125	beam shaping optics

- 127 lens
- 130 optical coupler
- 135 apertures
- 137 patterned aperture
- 5 140 light guide adaptor

CLAIMS:

1. A light therapy device for delivering light energy to a portion of a patient's body, comprising:
 - a) a light source, comprising one or more light emitters for providing input light;
 - b) a light coupling means for directing said input light into a light guide;
 - c) a flexible optically transparent light guide material, which comprises said light guide;
 - d) a light extraction means which is applied to a surface of said light guide material; wherein said light extraction means is positioned to provide light therapy treatment to one or more localized areas of said patient's body; and
 - e) a control means, which controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.
2. A light therapy device as in claim 1 wherein said light extraction means is a reflective optical diffuser layer.
3. A light therapy device as in claim 1 wherein said light extraction means comprises a micro-structured transmissive optical layer.
4. A light therapy device as in claim 1 wherein said light extraction means includes a light extraction layer and a mask.
5. A light therapy device as in claim 1 wherein said light extraction means is customizable to generally conform to the size and shape of the areas to be treated.
6. A light therapy device as in claim 1 wherein a clinician examines the wounds and transfers the shape and size information to said light extraction layer, and modifies said light extraction layer to aid illumination of the

wound area, and then attaches the customized light extraction layer to said light guide.

5 7. A light therapy device as in claim 6 wherein a digital camera is used to customize said light extraction means.

 8. A light therapy device as in claim 1 wherein said light guide has apertures to conform said light guide to body structures.

10 9. A light therapy device as in claim 1 wherein edges or corners of said light guide are modified to conform to local features of said patients' body.

 10. A light therapy device as in claim 9 wherein a reflective epoxy or adhesive, such as a silver impregnated epoxy, is applied to said edges.

 11. A light therapy device as in claim 1 wherein the device comprises polarization layers to irradiate said localized areas with polarized light.

20 12. A light therapy device as in claim 1 wherein said light source comprises one or more LEDs, lasers, lamps.

 13. A light therapy device as in claim 1 wherein said light source emits light within a spectral range of 400-1500 nm.

25 14. A light therapy device as in claim 1 wherein said light source emits red or IR light.

 15. A light therapy device as in claim 1 wherein said light guide material comprises a non-woven polymer material, such as a polyurethane, elastomer, or acetate.

16. A light therapy device as in claim 1 wherein said light source is temporally modulated within a frequency range encompassing 5 Hz to 5 kHz.

5 17. A light therapy device as in claim 1 wherein said light coupling means comprises beam shaping optics comprising a tapered light guide, a Fresnel lens, a cylinder lens, a lenslet array, or other appropriate optical components.

10 18. A light therapy device as in claim 1 wherein said light guide can be removed from said light source and replaced by another light guide.

19. A light therapy device as in claim 1 wherein said light extraction means includes an adaptor for hair.

15 20. A light therapy device as in claim 1 wherein said light source includes spectral filters.

20 21. A light therapy device as in claim 1 wherein said light guide is coated with hygienic layers, antibiotic layers, bio-chemical marker, or anti-tacky outermost surface.

22. A light therapy device as in claim 1 wherein light guide is a sheet, which can be of uniform thickness or wedged, with the thick end towards
25 said light source.

23. A light therapy device as in claim 1 wherein said light guide has a pre-formed or pre-molded shape.

30 24. A light therapy device as in claim 1 wherein said light guide is shaped like a face.

25. A light therapy device as in claim 1 wherein said light therapy device is modular, and can be disassembled between said light source and said light guide.

5 26. A light therapy device as in claim 1 wherein said light therapy device provides bio-sensors.

27. A light therapy device for delivering light energy to a portion of a patient's body comprising:
10 a) a light source, comprising one or more light emitters for providing input light;
b) a coupler for directing said input light into a light guide;
c) a flexible, optically transparent, light guide material, which comprises said light guide;
15 d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body;
e) a controller, which controls the light dosage relative to
20 intensity, wavelength, modulation frequency, repetition and timing of treatments; and
wherein said light therapy device is modular, and can be disassembled between the light source and the light guide.

28. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:
a) a light source, comprises an array of light emitters for providing input light;
b) a light coupler for directing said input light into a light
30 guide;
c) a flexible optically transparent light guide material, which comprises said light guide;

- 5 d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body;
- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters; and
- 10 wherein said light therapy device is modular, and can be disassembled between the light source and the light guide.

29. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:
- 15 a) a light source, comprises an array of light emitters for providing input light;
- b) a light coupler for directing said input light into a light guide;
- c) a flexible optically transparent light guide material, which comprises said light guide;
- 20 d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy;
- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments,
- 25 and other parameters;
- wherein said light extraction layer is pre-assembled onto said light guide; and
- wherein said light therapy bandage is applied to said patient's body such that said light extraction layer is positioned to provide light
- 30 therapy treatment to one or more localized areas of said patient's body.

30. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

a) a light source, comprises one or more light emitters for providing input light;

b) a light coupler for directing said input light into a light guide;

c) a flexible optically transparent light guide material, which comprises said light guide;

d) a light extraction layer which is a reflective optical diffuser applied to the outer surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body; and

e) a control means, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

31. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

a) a light source, comprises one or more light emitters for providing input light;

b) a light coupler for directing said input light into a light guide;

c) a flexible optically transparent light guide material, which comprises said light guide;

d) a light extractor which is a transparent micro-structured optical layer applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extractor is customized for shape, size, and position to provide light therapy treatment to one

or more localized areas of said patient's body; and

e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

- 5 32. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:
- a) a light source, comprises one or more light emitters for providing input light;
- b) a light coupler for directing said input light into a light
- 10 guide;
- c) a flexible optically transparent light guide material, which comprises said light guide;
- d) a light extractor which comprises a micro-structured optical layer applied to a surface of said light guide material, and a mask, such
- 15 that light exits said light guide and is available for a light therapy; wherein said mask portion of said light extractor is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body; and
- e) a controller, which controls the light dosage relative to
- 20 intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

33. A method for providing light therapy using a light guide bandage for treatment of one or more areas of a patient, comprising:
- 25 a) examining the treatment areas to determine the condition of the tissues therein;
- b) determining the size and extent of the treatment areas to be treated with light therapy;
- c) customizing a light extraction layer onto a light guide
- 30 bandage in accordance with the treatment areas;
- d) combining said light guide bandage with a light source and a controller;

e) assembling the light guide bandage with other bandage elements; and

f) setting control parameters for the light therapy.

- 5 34. A method for providing light therapy using a light guide bandage for treatment of one or more areas of a patient, comprising:
- a) examining the treatment areas to determine the condition of patient tissues;
- b) determining the size and shape of the treatment areas to
10 be treated with light therapy;
- c) providing a light guide bandage, which includes a light source and a controller, with a light extraction layer that generally corresponds to said treatment areas;
- d) assembling said light guide bandage with other bandage
15 elements; and
- e) setting control parameters for the light therapy.

35. A method for providing light therapy as in claim 34, wherein said light guide therapy device delivers repeated controlled treatments
20 over a course of time.

36. A method for providing light therapy as in claim 34, wherein at least part of said light guide bandage is modified or replaced during treatment of said patient.

- 25 37. A light therapy device for delivering light energy to a portion of a patient's body, comprising a light source that consisting of one or more light emitters for providing input light to a light guide, wherein said light guide comprises a flexible optically transparent light guide material, wherein said
30 light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of

said light guide to then provide light therapy treatment to one or more localized areas of said patient's body.

38. A light therapy device for delivering light energy to tissues requiring treatment, comprising a light source consisting of one or more light emitters for providing input light to a flexible transparent optical substrate material, wherein said light therapy device is provided with a light extraction means that is spatially patterned across one or more portions of said device so as to direct light out of said device to then provide light therapy treatment to one or more localized areas of said tissues..

39. A light therapy device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprising one or more light emitters for providing input light for a light guide;
- b) a flexible optically transparent light guide material, which comprises said light guide; and
- c) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said patient's body.

40. A light therapy device for delivering light energy to tissues requiring treatment, comprising:

- a) a light source, comprising one or more light emitters for providing input light for a light guide;
- b) a flexible optically transparent light guide material, which comprises said light guide;
- c) a tissue interface layer, which is attached to a surface of said light guide, and which is proximate to tissues; and

d) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said tissues.

41. A light therapy device for delivering light energy to a portion of a patient's body, comprising:

a) a light source, comprising one or more light emitters;

b) a light coupling means comprising one or more optical fibers for coupling said input light from said light source into a light guide;

c) a flexible optically transparent light guide material, which comprises said light guide; and

d) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said patient's body.

42. A light therapy device as in claim 1 wherein said light coupling means comprises one or more optical fibers for coupling said input light from said light source into said light guide.

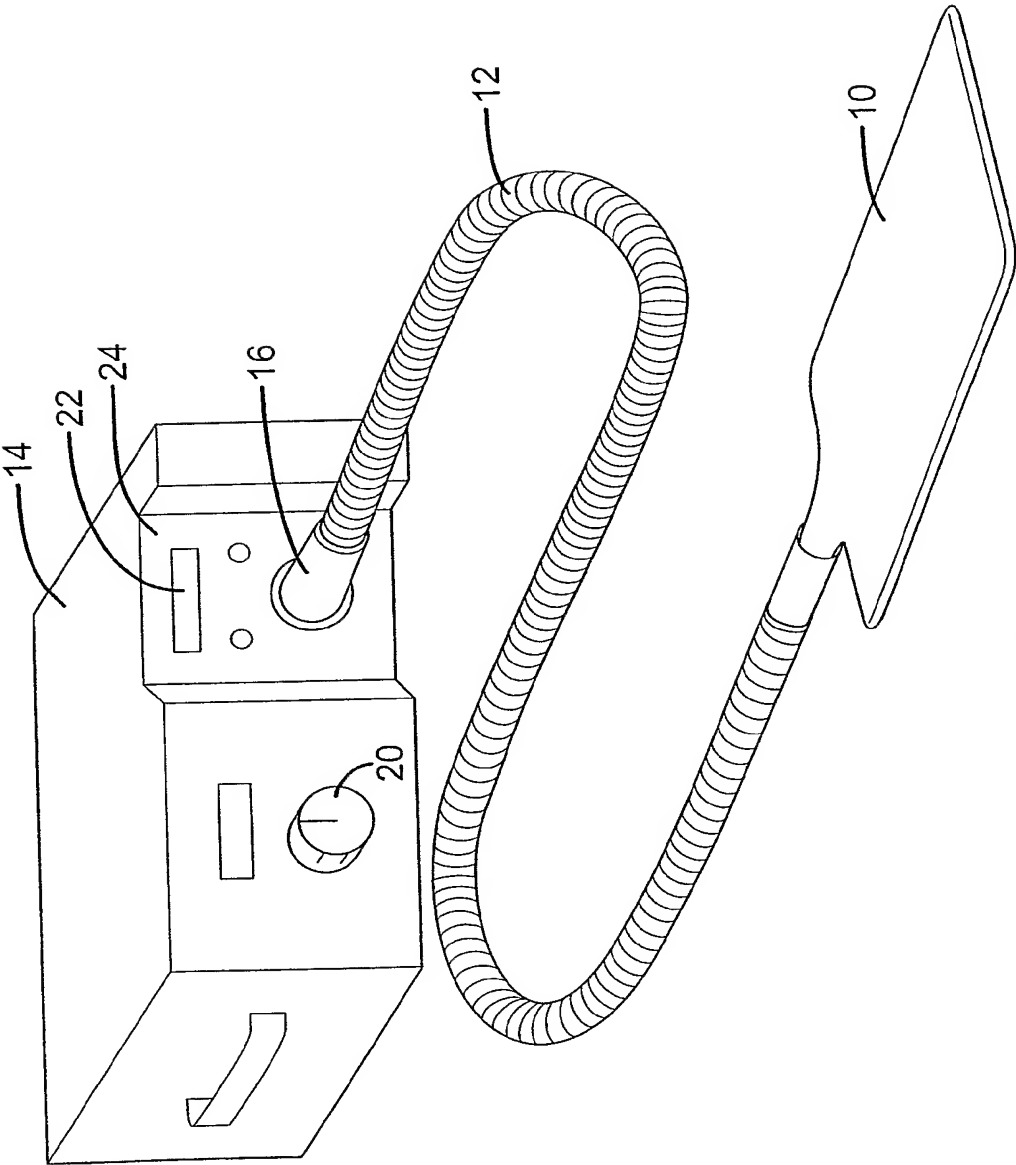


FIG. 1
PRIOR ART

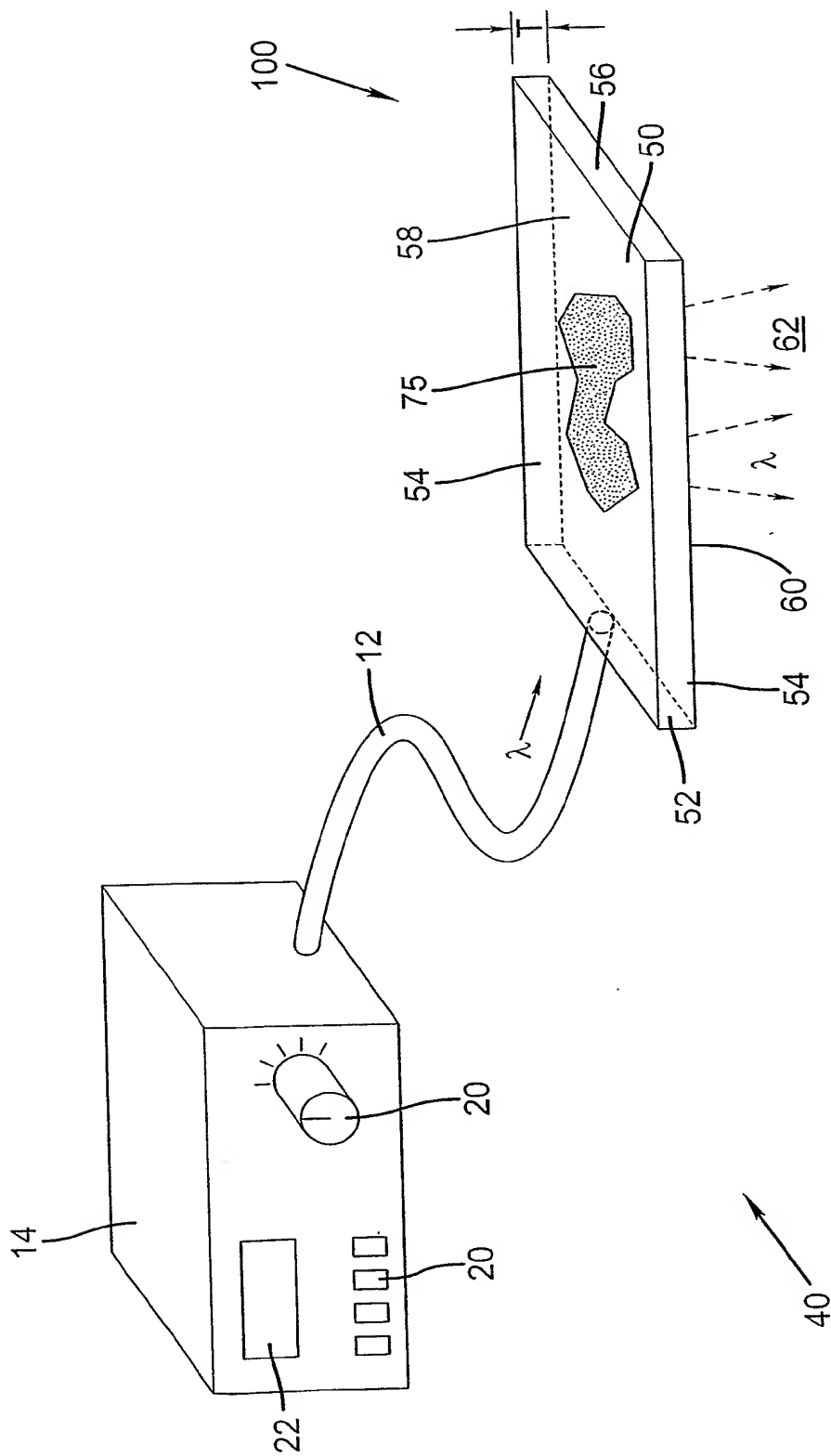


FIG. 2

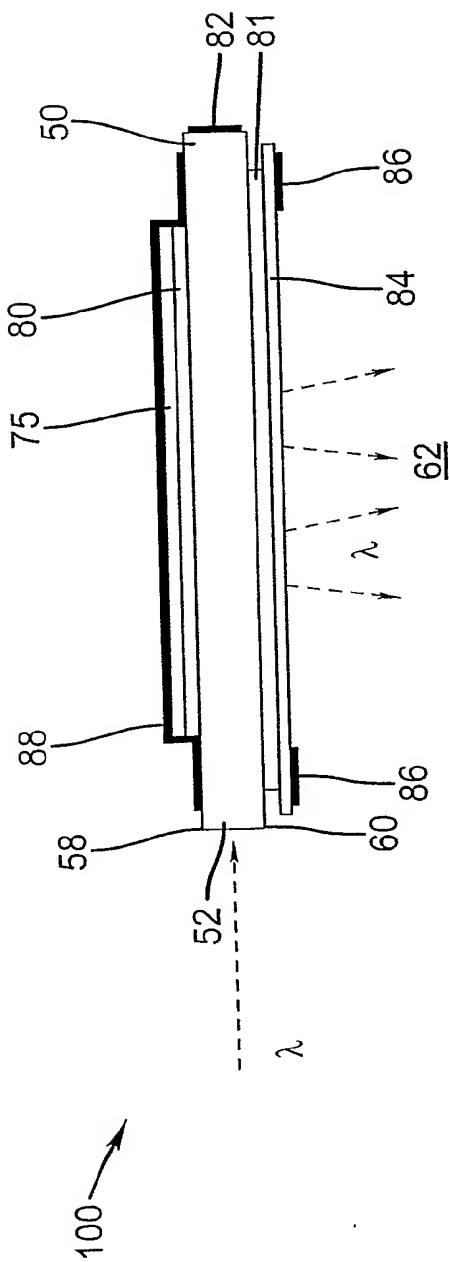


FIG. 3a

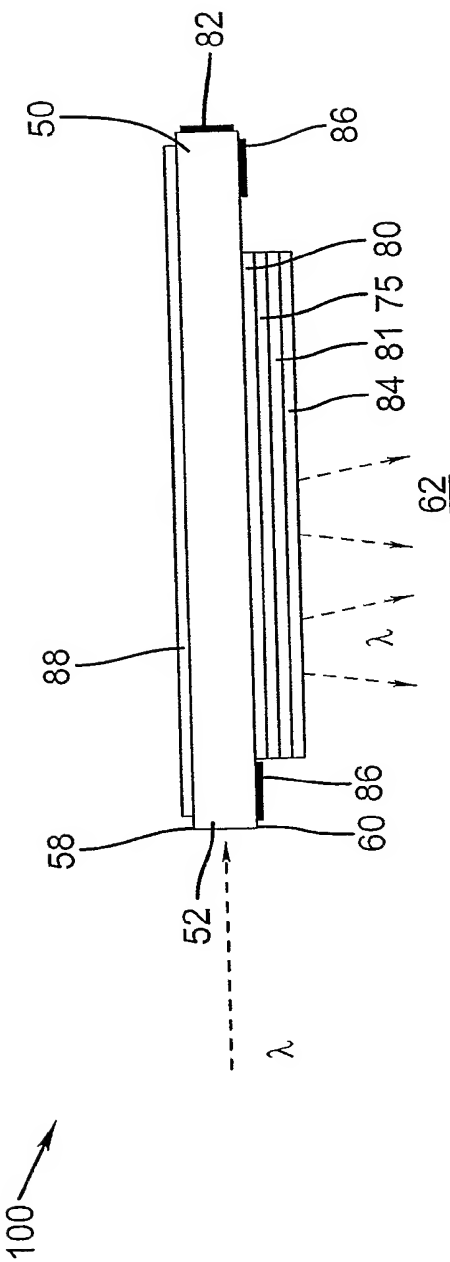


FIG. 3b

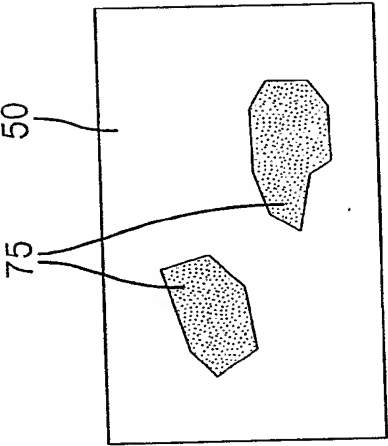


FIG. 4a

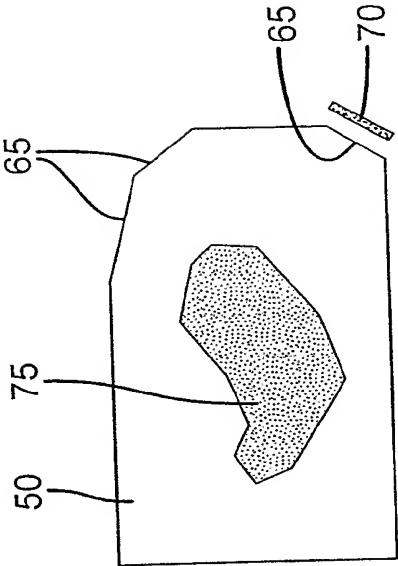


FIG. 4b

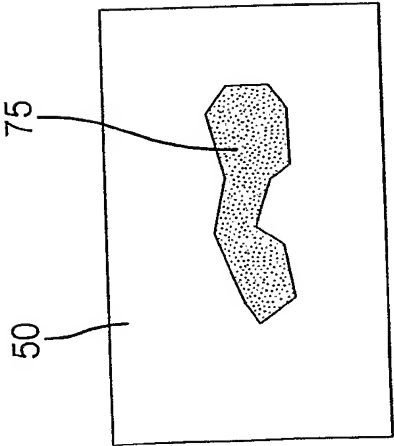


FIG. 4c

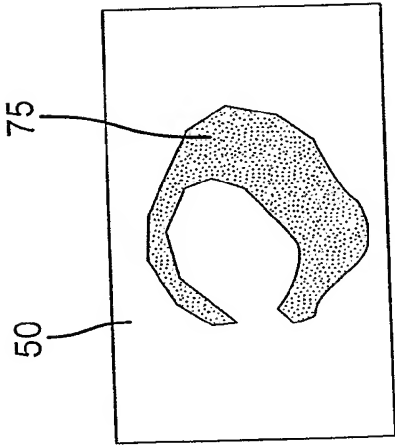


FIG. 4d

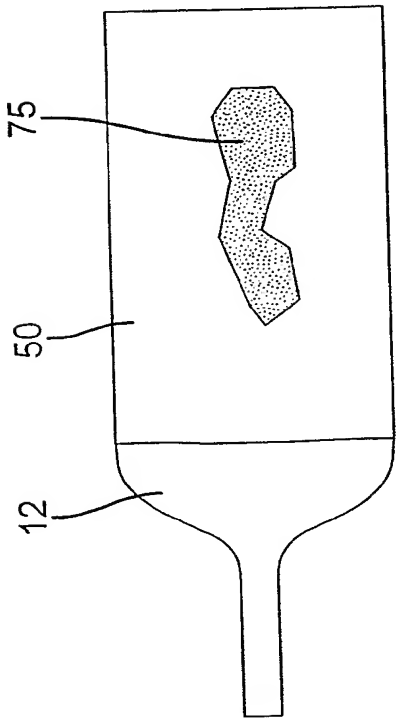


FIG. 5a

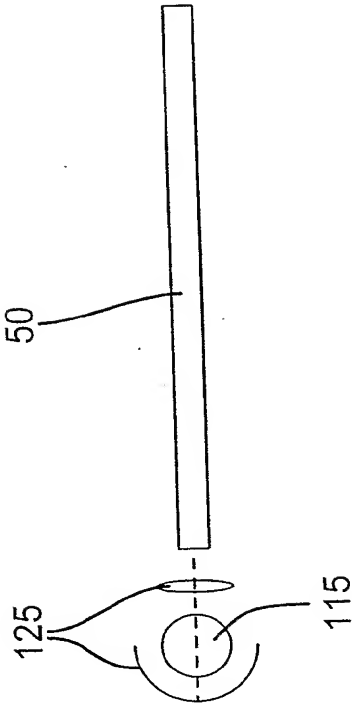


FIG. 5b

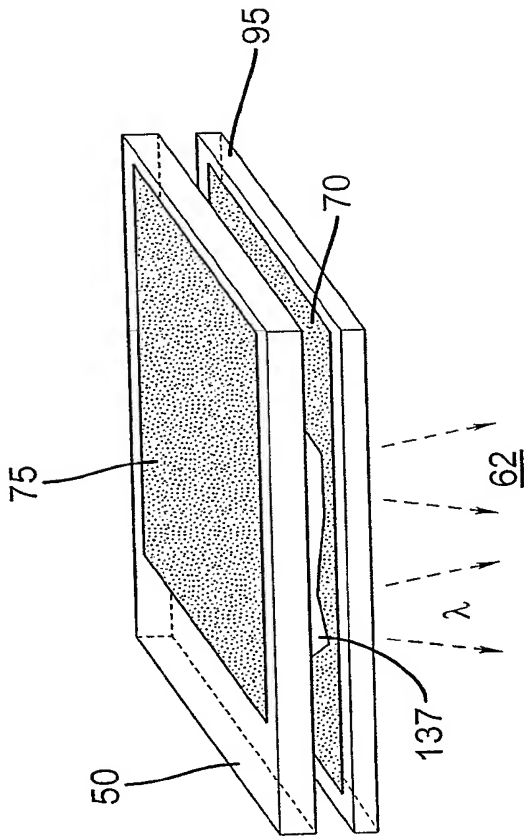


FIG. 5c

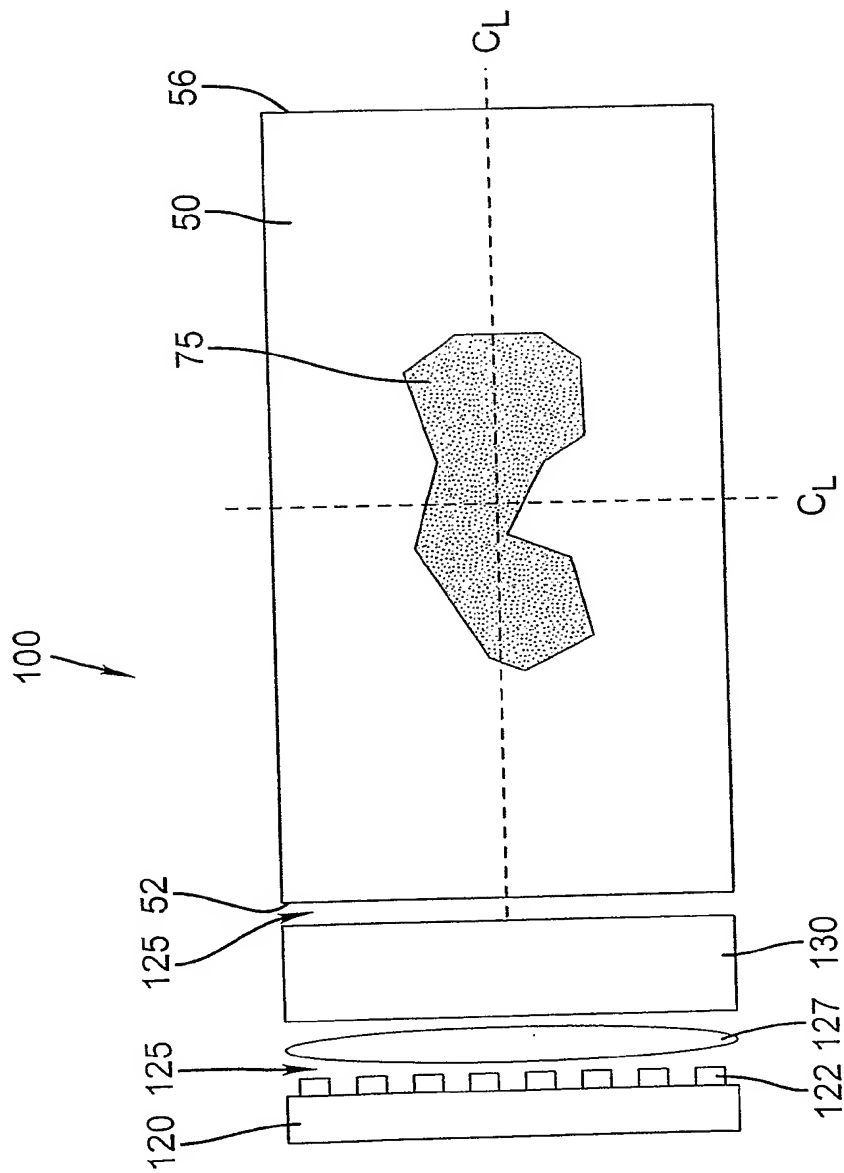


FIG. 6a

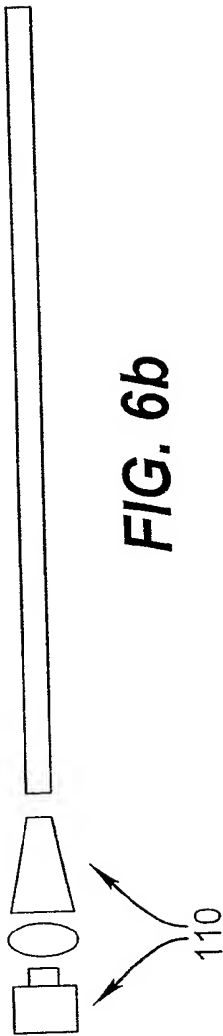


FIG. 6b

7/9

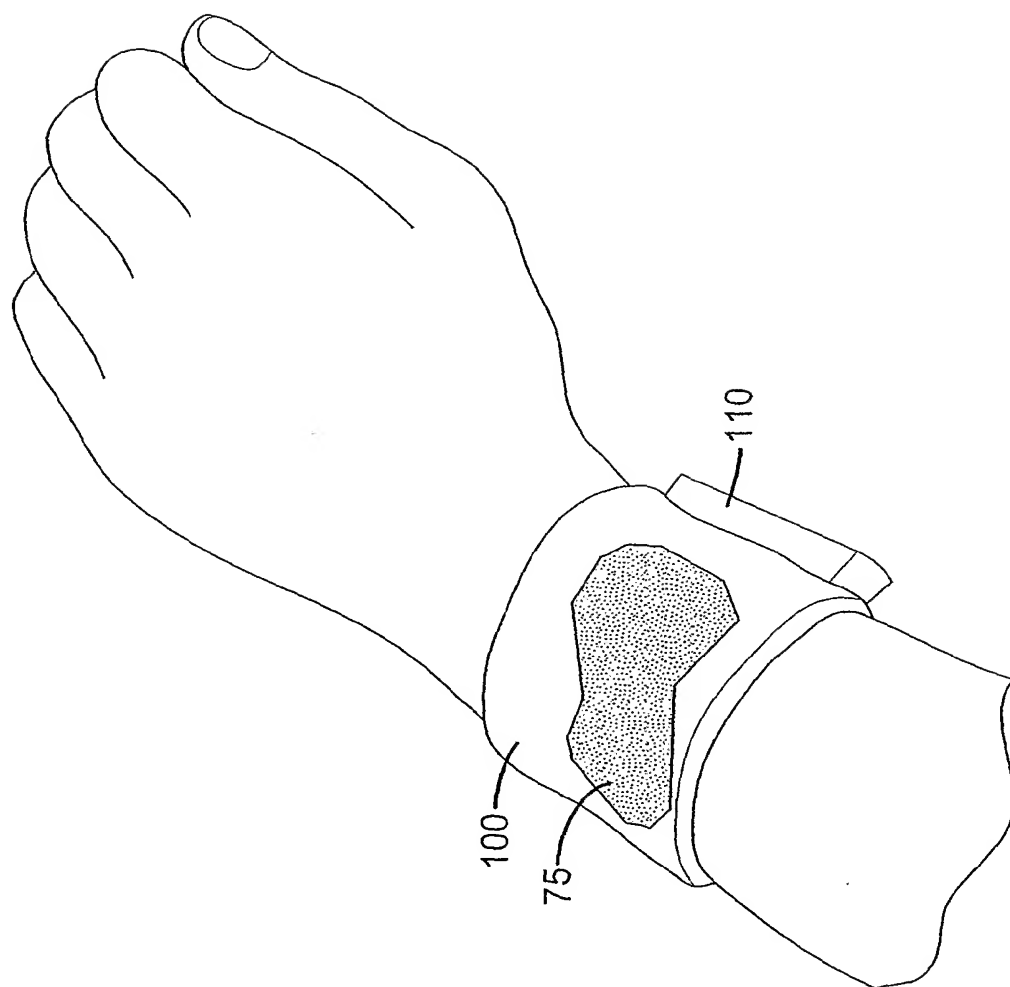


FIG. 7

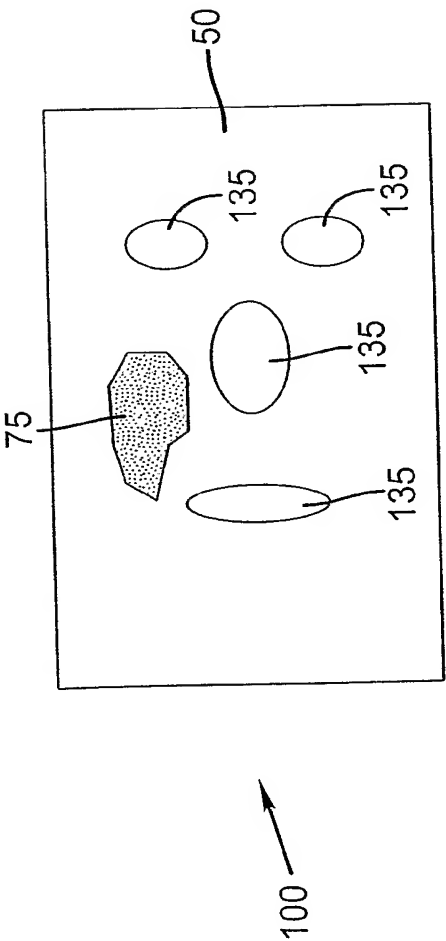


FIG. 8a

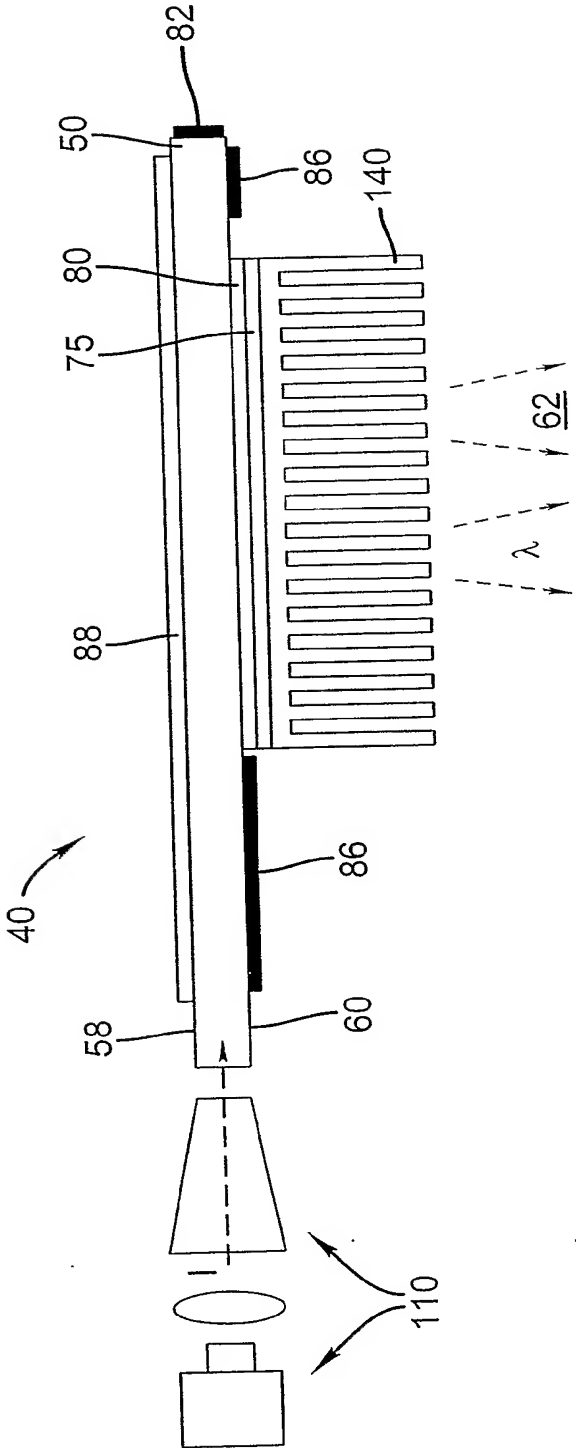


FIG. 8b

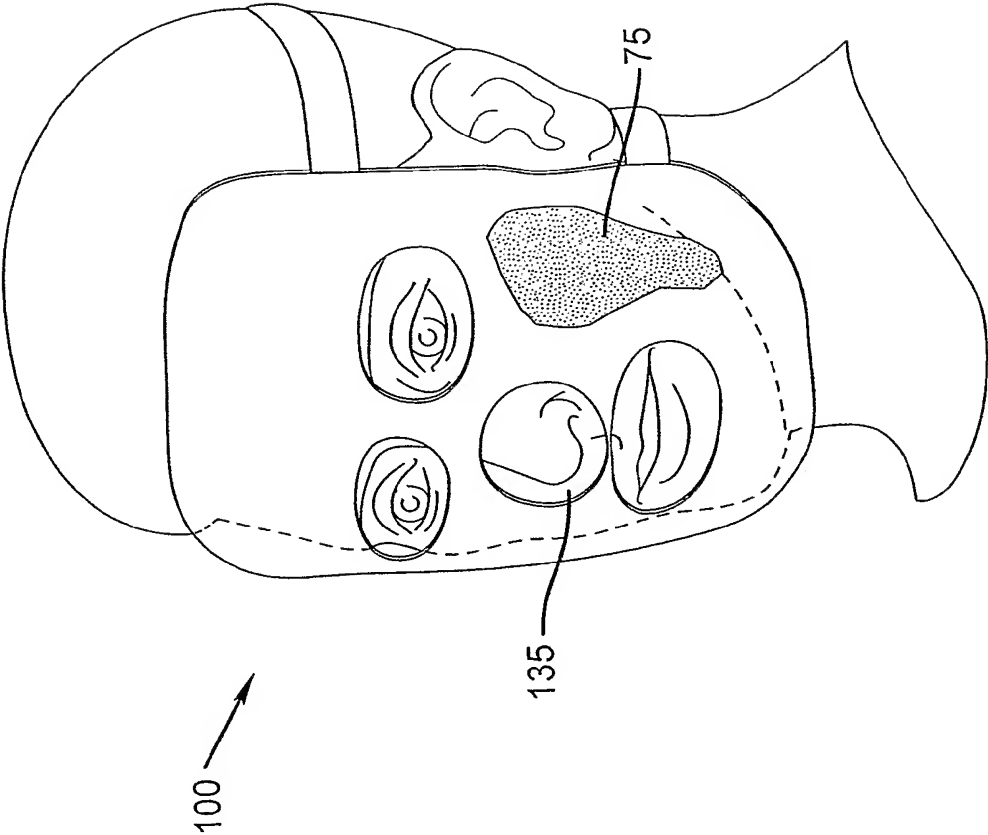


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/008210

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/043543 A (PALOMAR MEDICAL TECHNOLOGIES, INC) 27 May 2004 (2004-05-27) page 3, line 13 - page 6, line 15 page 8, line 4 - line 8 page 15, line 7 - page 16, line 17 page 18, line 19 - line 30 page 19, line 21 - page 20, line 10 table 1	1-5, 12-14, 17,20, 22-24, 26-32, 37-42
X	WO 98/43703 A (PRESCOTT, MARVIN, A) 8 October 1998 (1998-10-08) claim 1 page 9, line 3 - line 5 ----- -/--	1,11

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 June 2006

Date of mailing of the international search report

30.08.2006

Name and mailing address of the ISA/

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Authorized officer

Lohmann, S

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/008210

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 096 066 A (CHEN ET AL) 1 August 2000 (2000-08-01) cited in the application abstract column 6, line 48 - line 64 figure 8 -----	1,16
X	US 2004/044384 A1 (LEBER LELAND C ET AL) 4 March 2004 (2004-03-04) paragraph [0063] -----	1,18,25
X	US 5 400 425 A (NICHOLAS ET AL) 21 March 1995 (1995-03-21) cited in the application abstract figure 2 -----	1,3,5, 18,20,25
X	US 6 569 189 B1 (AUGUSTINE SCOTT D ET AL) 27 May 2003 (2003-05-27) cited in the application abstract figures 1,2,9 -----	1,5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/008210

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 33-36
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 6, 7
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5, 11-14, 16-18, 20, 22-32, 37-42

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 33-36

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 6, 7

No technical features, merely method steps of using the claimed device
(Art. 6 PCT)

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 11-14, 16-18, 20, 22-32, 37-42

A light therapy device comprising a light source, a light coupling means, a flexible optically transparent light guide material which comprises a light guide, a light extraction means and a control means, furthermore inter alia defining particular features of said light extraction means.

2. claims: 8-10, 15, 21

A light therapy device comprising a light source, a light coupling means, a flexible optically transparent light guide material which comprises a light guide, a light extraction means and a control means, furthermore inter alia defining particular features of said light guide.

3. claim: 19

A light therapy device comprising a light source, a light coupling means, a flexible optically transparent light guide material which comprises a light guide, a light extraction means and a control means, said light extraction means furthermore including an adaptor for hair.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/008210

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004043543	A	27-05-2004	AU 2003291469 A1 CA 2505559 A1 CN 1738663 A EP 1567227 A1 JP 2006506126 T	03-06-2004 27-05-2004 22-02-2006 31-08-2005 23-02-2006
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US 6569189	B1	27-05-2003	US 6080189 A US 6440156 B1	27-06-2000 27-08-2002

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

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11/347,672 3 February 2006 (03.02.2006) US

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(72) Inventors; and

(75) Inventors/Applicants (for US only): MIRKOV, Mirko,
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[US/US]; 2 Jordan Road, Hopkinton, MA 01748 (US).

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kind of national protection available): AE, AG, AL, AM,
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(patent), UZ, VC, VN, YU, ZA, ZM, ZW.

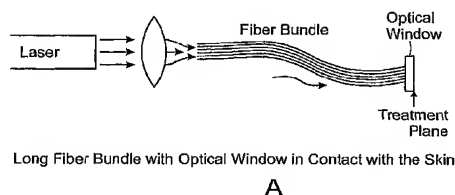
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GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
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RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
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Published:

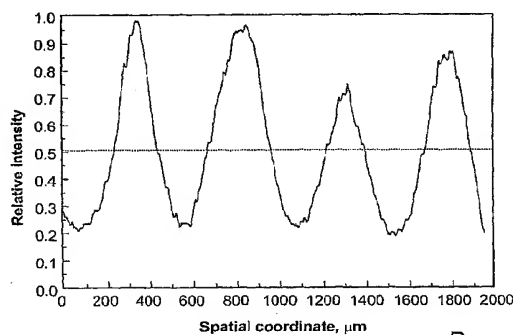
— with international search report

[Continued on next page]

(54) Title: METHODS AND SYSTEMS FOR LASER TREATMENT USING NON-UNIFORM OUTPUT BEAM



A



B

(57) Abstract: Methods and apparatus for treatment, such as skin rejuvenation treatment, use non-uniform laser radiation. A high-intensity portion of the laser radiation causes collagen destruction and shrinkage within select portions of the treatment area, while a lower-intensity portion of the radiation causes fibroblast stimulation leading to collagen production across other portions of the treatment area. An output beam from a laser source, such as an Nd:YAG laser, is coupled into an optical system that modifies the beam to provide a large-diameter beam having a nonuniform energy profile, comprised of a plurality of high-intensity zones surrounded by lower-intensity zones within the treatment beam. The higher-intensity zones heat select portions of the target tissue to temperatures sufficient for a first treatment (e.g. collagen shrinkage), while the lower-intensity zones provide sufficient energy for a second treatment (e.g. stimulated collagen production). A large area of tissue, preferably 7-10 mm in diameter, can be treated simultaneously, while minimizing the risk of burning or other damage to the skin. In one embodiment, the invention uses a fiber bundle to provide a non-uniform energy output beam, hi another embodiment, the invention uses a diffractive lens array to produce the non-uniform output beam. A cooling system can also be integrated with the laser treatment system. A pulse light source can also be integrated with the laser treatment system in a combined skin rejuvenation therapy.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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METHODS AND SYSTEMS FOR LASER TREATMENT USING NON-UNIFORM OUTPUT BEAM

RELATED APPLICATION

This application is a continuation-in-part of U.S. Application
5 No. 11/347,672, filed February 3, 2006, which claims the benefit of U.S. Provisional
Application No.: 60/673,914, filed April 22, 2005, the entire teachings of which are
incorporated herein by reference.

BACKGROUND OF THE INVENTION

Plastic surgeons, dermatologists and their patients continually search for new
10 and improved methods for treating the effects of an aging skin. One common
procedure for rejuvenating the appearance of aged or photodamaged skin is laser
skin resurfacing using a carbon dioxide laser. The carbon dioxide laser energy is
absorbed by tissue water causing vaporization of the outer skin layer. Carbon
dioxide lasers have been utilized for approximately three decades. However it has
15 only been the past few years that these lasers have been arranged to remove only thin
tissue layers with minimal heat damage to the surrounding skin. While carbon
dioxide lasers may remove about 150 microns of skin, that skin may take a month or
more to heal under such a procedure.

Er:YAG lasers have been utilized to ablate even thinner layers of tissue than
20 carbon dioxide layers. However they lack the coagulation characteristics and thus
allow more bleeding than a carbon dioxide laser during use.

Non-ablative skin rejuvenation is a methodology which does not take the top
layer of skin off, but which uses a deep-penetrating laser to treat the layers of skin
beneath the outer epidermal layer, treating unsightly vascular and pigmented lesions,
25 and shrinking and modifying the underlying collagen, tightening the skin and
reducing wrinkles to provide a more youthful appearance. This methodology
however, has a low efficiency, and an aggressive cooling method must be used on to

the skin so as to minimize damaging the top or upper layer thereof and also to minimize pain generation. The “fluence” or energy density used is greater than 10 joules per square centimeter and to be more effective this fluence often reaches 30 Joules per square centimeter. This level of energy often causes pain and epidermal damage.

United States Published Patent Application No. 2002/0161357 A1, by Anderson *et al.*, discusses a method and apparatus for performing therapeutic treatment on a patient’s skin by using focused radiation beams to create “islands” of treatment/damage within untreated portions of the patient’s skin. However, the parameters of the treatment beam in this method are not optimal for skin rejuvenation treatment.

Yet another treatment method is disclosed in U.S. Patent No. 6,077,294 to Cho *et al.*, the entire teachings of which are incorporated herein by reference. This patent describes a system and methodology for noninvasive skin treatment that utilizes a pulsed dye laser having a wavelength of about 585 nanometers (nm), and an energy of less than 5 Joules per square cm. In contrast to earlier techniques which used higher-energy pulses to damage and “shrink” the collagen below the epidermis, the relatively lower energies of the beams in the ‘294 patent are designed to stimulate the collagen to regenerate and “fill in” valleys of the skin for a younger more clearer skin.

SUMMARY OF THE INVENTION

The present invention relates to methods and apparatus for treatment using non-uniform laser radiation. Preferably, the invention is used for skin rejuvenation treatment, in which a high-intensity portion of the laser radiation causes collagen destruction and shrinkage within select portions of the treatment area, while a lower-intensity portion of the radiation causes fibroblast stimulation leading to collagen production across other portions of the treatment area.

Preferably, the method and system of the invention utilize a solid-state laser source, such as an Nd:YAG laser. The output beam from the laser source is coupled into an optical system that modifies the beam to provide a large-diameter beam

having a non-uniform energy profile, comprised of a plurality of high-intensity zones surrounded by lower-intensity zones within the treatment beam. The higher-intensity zones heat select portions of the target tissue to temperatures sufficient for a first treatment (*e.g.* collagen shrinkage), while the lower-intensity zones provide
5 sufficient energy to the surrounding tissue for a second treatment (*e.g.* stimulated collagen production). Thus, a large area of tissue, preferably 7-10 mm in diameter, can be treated simultaneously, while minimizing the risk of burning or other damage to the skin.

In one embodiment, the invention uses a fiber bundle to provide a non-uniform energy output beam. In another embodiment, the invention uses a
10 diffractive lens array to produce the non-uniform output beam.

A method of treating human skin in accordance with one aspect of the invention comprises generating an output beam from a laser source, such as an Nd:YAG laser; coupling the beam into an optical system that modifies the beam to
15 provide a treatment beam having a non-uniform energy profile, the treatment beam comprised of a plurality of high-intensity zones surrounded by low-intensity zones within the treatment beam; and directing the treatment beam to a target tissue area such that the high-intensity zones heat select portions of the target tissue to temperatures sufficient for a first treatment, while the lower-intensity zones provide
20 sufficient energy to the surrounding tissue for a second treatment. Preferably, the first treatment comprises collagen shrinkage and the second treatment comprises collagen stimulation. The output beam can have a wavelength between about 1.3 to 1.6 microns, and preferably between about 1.41 and 1.44 microns, and a pulse duration between 0.1 and 100 milliseconds, and preferably between about 1 and 5
25 milliseconds. The average fluence of the treatment beam can be less than about 10 J/cm². Generally, the average fluence of the treatment beam is between about 5-6 J/cm². The average fluence in the lower-intensity zones is generally on the order of 2-3 J/cm².

The optical system can comprise a fiber bundle, having 1000 to 2000
30 separate fibers, for instance, and a focusing lens for coupling the beam into the fiber bundle. An optical window, preferably between 1 and 5 mm thick, can be located at

the distal end of the bundle, the optical window permitting the beams emitted from each fiber in the bundle to diverge and partially overlap with one another before they reach the target tissue. In certain embodiments, a transport fiber can carry the output beam from the laser source to the fiber bundle, and the fiber bundle can be located in
5 a handpiece.

In another embodiment, the optical system can comprise a diffractive lens array, preferably comprised of about 2000 or less lenses, arranged in an optical path between a laser source and the treatment area, such that each lens in the array provides a high-intensity zone surrounded by a low intensity zone of radiation. Each
10 lens in the array can have a diameter of between about 150 and 450 microns, and the entire lens array can have a diameter of between about 7 and 10 mm. Preferably, the average fluence of the laser output beam is less than about 10 J/cm².

In another embodiment, a laser system of the invention comprises a laser source that generates an output beam; and an optical system that modifies the output
15 beam to provide a treatment beam having a non-uniform energy profile, the treatment beam being comprised of a plurality of high-intensity zones surrounded by low-intensity zones within the treatment beam, such that the high-intensity zones heat select portions of a target tissue to temperatures sufficient for a first treatment, while the lower-intensity zones provide sufficient energy to the surrounding tissue
20 for a second treatment. The laser source can be an Nd:YAG laser, and generally produces an output beam having a wavelength between about 1.3 to 1.6 microns, and preferably between about 1.41 and 1.44 microns, and a pulse duration between 0.1 and 100 milliseconds, preferably between about 1 and 5 milliseconds. The optical system can comprise a fiber bundle, preferably with an optical window between the
25 distal end of the bundle and the target tissue. Alternatively, the optical system can include a diffractive lens array in the optical path between the source and the treatment area, such that each lens in the array provides a high-intensity zone surrounded by a low intensity zone of radiation.

According to another embodiment, a laser system comprises a laser source
30 that generates an output beam; a fiber bundle comprising a plurality of individual fibers, the fiber bundle having a proximal end and a distal end; a focusing lens for

coupling the output beam into a proximal end of the fiber bundle; and an optical window at the distal end of the fiber bundle, the optical window permitting the beams emitted from each fiber in the bundle to diverge as the beam passes through the optical window so that each beam partially overlaps with the beam(s) from adjacent fibers in the bundle. The optical window can comprise a transparent material, such as glass, or could comprise a spacer having an empty space between the distal end of the fiber bundle and the treatment area.

According to yet another embodiment, a laser system comprises a laser source that generates an output beam; and a diffractive lens array arranged in an optical path between a laser source and a treatment area, such that each lens in the array provides a high-intensity zone surrounded by a low intensity zone of radiation.

In certain embodiments, a laser system and method of the invention comprises a tip housing that contains the optical system for providing a treatment beam having a non-uniform energy profile, a distal end of the tip housing being adapted to contact against the target tissue area of the patient; and a conduit that carries cooled air to the tip housing, the conduit comprising an outlet that is angled to direct cooled air onto the distal end of the tip housing.

In further embodiments, a laser system of the invention further comprises a pulse light system, such as a flashlamp system, integrated with the laser system, for treating pigmented lesions.

The present invention provides a laser treatment which covers a large area of the patient, is characterized by high-absorption of the laser radiation and lower peak energies, which results in minimal risk of skin damage. In one aspect, the present invention advantageously accomplishes stimulated collagen production as well as collagen shrinkage simultaneously in a single treatment area. In addition to skin rejuvenation treatment, the principles of the invention can also be extended for use in other types of optical radiation treatments, including, without limitation, treatment of acne, hair removal, and treatment of vascular or pigmented lesions.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which
5 like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

Fig. 1A illustrates a laser treatment system comprising a fiber bundle and optical window;

10 Fig. 1B is a plot of the beam profile on the skin for the laser treatment system of Fig. 1A;

Fig. 2 illustrates a laser treatment system comprising a short fiber bundle with expanded distal face;

Fig. 3 shows a diffractive lens having four levels;

15 Fig. 4 shows a diffractive lens having two levels;

Fig. 5 shows a diffractive lens with eight levels;

Fig. 6 shows a diffractive lens array having a hexagonal pattern;

Fig. 7 shows a diffractive lens array having an elongated hexagonal pattern;

Fig. 8 shows a treatment beam profile for a diffractive lens array;

20 Fig. 9 shows a plot of the relative hot area fluence factor, F_h/F_{av} , as a function of the relative diameter of the central hot area, d/D for a diffractive lens array in accordance with one aspect of the invention;

Fig. 10 shows the temperature profile of skin treated with a non-uniform output beam from a diffractive lens array;

25 Fig. 11 shows a tip of a laser treatment handpiece having a cooling mechanism; and

Fig. 12 shows an integrated laser and pulse light system for skin rejuvenation treatment.

DETAILED DESCRIPTION OF THE INVENTION

30 A description of preferred embodiments of the invention follows.

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As shown in Fig. 1A, the apparatus includes a laser source that emits an output beam. The beam is coupled into a bundle of optical fibers using one or more focusing lenses. The bundle preferably contains between 1000 and 2000 separate fibers. Typically, each fiber has a diameter of about 100-200 microns. The output
5 laser beam is thus directed to 1000-2000 smaller beams, each of which traverses the length of the fiber bundle in individual optical fibers. The fiber bundle terminates at its distal end at an optical window that can be held in direct contact with the patient's skin. The window is approximately 1-5 mm thick, and protects the output
10 face of the fiber bundle from contamination, and also permits the beam emitted from each fiber to diverge before it reaches the patient's skin, preferably so that each beam partially overlaps with the beam(s) from adjacent fibers in the bundle.

The fibers in the bundle can be packed together tightly, or can be spaced apart from each other using mechanical spacers. The use of mechanical spacers at the distal end of the bundle spreads the energy from the bundle over a larger area,
15 and helps to reduce the pain sensation for the patient. In general, the combined spot size on the skin from all the fibers in the fiber bundle is between approximately 7 and 10 mm in diameter.

In a preferred treatment method for the embodiment of Fig. 1A, the laser source, which is preferably an Nd:YAG laser, produces an output laser pulse having
20 a wavelength of between 1.3 and 1.6, preferably between about 1.40 and 1.44 microns, and a pulse duration of between 0.1 and 100 milliseconds, preferably between about 1 and 5 milliseconds. Because the laser operates at wavelengths that are well-absorbed by the skin, the laser can operate at relatively low energies, and minimize the risk of burning or damage to the skin.

25 In operation, the optical window is held against the skin of the patient, and the laser source is energized to produce a pulse of laser light that travels from the source through the fiber bundle and the optical window, and penetrates into the patient's skin. Since the optical window is approximately 1-5 mm thick, the window also serves as a spacer between the output end of the fiber bundle and the skin of the
30 patient. Thus, as the laser light is emitted from each fiber in the bundle, the light is permitted to diverge as it travels through the window to the patient's skin. In a

preferred embodiment, the fibers are approximately 100-200 microns in diameter, and the beam emitted from each fiber, after passing through the window, produces a spot between 150-900 microns in diameter on the patient's skin. Because of the diverging nature of light emitted from an optical fiber, the light at the center of each spot will be relatively high-energy light, while the light at the periphery of each spot will have significantly lower energy. Thus, over a combined spot size of 7 to 10 mm for the entire fiber bundle, there are approximately 1000 to 2000 smaller treatment spots, generally about 150-900 microns in diameter, each consisting of a higher-fluence "hot spot" at the center of the spot surrounded by a lower-fluence "cooler zone" of radiation. The energy at the central "hot spot" is sufficient to shrink the underlying tissue, damage the collagen and produce collagen shrinkage. In general, the energy at the high-intensity zones, or "hot spots" is sufficient to raise the temperature of the target tissue to 70° C or higher. However, the radiation in "cooler zone" surrounding the hot spot is generally not sufficient to damage the tissue and cause collagen shrinkage in the tissue underlying these areas. In these lower-intensity "cooler zones," the energy provided will only raise the temperature of the skin by a few degrees (or perhaps result in no appreciable temperature rise), and thus will not damage or even "shock" the tissue. However, this lower-intensity radiation is generally more appropriate or preferred to stimulate the fibroblasts in the tissue to produce collagen and "fill in" the skin for a younger more clearer skin

In a preferred embodiment, the fibers in the bundle are arranged so that the spot sizes of radiation from each fiber about or partially overlap with the spots from the adjacent fibers in the bundle on the patient's skin. In this way, the invention can simultaneously provide two modes of skin rejuvenation treatment: higher-energy collagen shrinkage treatment in the "hot spots" at the center of each output spot from the fiber bundle, and overall stimulated collagen production throughout the entire area of the combined fiber-bundle output beam.

An example of a laser treatment method using a fiber bundle delivery system is illustrated in Fig. 1B, which is a plot of the relative intensity on the skin as a function of location on the skin for four fibers in the bundle. In practice, the fiber bundle will consist of 1000-2000 individual fibers, in a regularly-spaced

arrangement to form a bundle. In this embodiment, the center-to-center distance between adjacent fibers in the bundle is approximately 500 microns. The diameter of each fiber is approximately 200 microns, and the numerical aperture (NA) of the fibers is approximately 0.2. The total diameter of the fiber bundle is approximately 9 millimeters. The laser energy emitted from each fiber diverges as it passes through the transparent window, so that the spot size on the skin from each fiber is at least about 250 microns in diameter. Thus, the spots from each fiber generally abut or partially overlap with the spots from the adjacent fibers in the bundle. This is shown in Fig. 1B, where it can be seen that the whole area is treated with at least a low-intensity pulse, while the areas at the center of each spot receive a significantly higher dose of energy. The dotted line represents the average intensity throughout the treatment area. In this example, the peak fluence on the skin at the center of each spot is approximately 9 J/cm^2 , while the fluence at the periphery of each spot is approximately 2 J/cm^2 . The total area fluence is approximately 5 J/cm^2 .

The fluence(s) received at various portions of the treatment area can be varied and controlled by, for instance, raising or lowering the total energy output from the laser source, changing the center-to-center distances between fibers in the bundle, using different diameter fibers, using fibers with a different NA to change the divergence of the beam and/or altering the thickness of the optical window to allow for a greater or lesser amount of beam divergence. The beam profile can thus be optimized for a variety of different conditions and laser treatment methods.

Fig. 2 shows yet another embodiment that is similar to the embodiment of Fig. 1, except that instead of a long-fiber bundle coupling the laser output beam from the source to the optical window, this embodiment uses a single transport fiber to carry the laser energy from the laser source to a handpiece containing a shorter fiber bundle. At the handpiece, the output laser pulse from the single fiber is coupled into the short fiber bundle. As in the prior embodiment, the short fiber bundle is comprised of a plurality of separate optical fibers, preferably 1000 to 2000 fibers. The short fiber bundle has a smaller bundle diameter at its proximal end to allow the output light from the single transport fiber to efficiently couple into the bundle. The fiber bundle "fans out" from its proximal end to its distal end, using, for example,

mechanical spacers, to provide an expanded face at its output. Preferably, the expanded face has a diameter of between approximately 7 to 10 mm, and is coupled to an optical window, as in the embodiment of Fig. 1. The embodiment of Fig. 2 preferably uses the same treatment parameters as those described in connection with
5 Fig. 1.

Turning now to Figs. 3-8, yet another embodiment of the invention is illustrated which uses a diffractive lens array to provide non-uniform heating in the target tissue. A multilevel diffractive lens consists of a number of concentric rings made of optically transparent material with variable thicknesses. The top surface of
10 each concentric ring is flat so the refractive effects are negligible. The variable-thickness rings give rise to a spatial phase delay pattern on a propagating incident optical beam. The propagating optical beam carries the spatial phase delay pattern past the plane of the diffractive lens and produces an illumination pattern of spatially variable optical intensity. The optical intensity is high at geometrical points that
15 meet the conditions for constructive interference and low at the points that meet the conditions for destructive interference. In general the design of a diffractive lens is optimized so that the principal diffraction maximum (or minimum) would be on the optical axis at a distance f from the plane of the lens. The distance f is the focal length of the lens. In general the goal of the diffractive lens design is to increase the
20 fraction of the incident power in the principal diffraction maximum. However, that fraction is always less than 1 depending on the number of levels, the F -number of the lens and other design parameters. In fact, it is possible to design the diffractive lens pattern so that any fraction (less than 1) of the incident power would be in the principal maximum and the rest of the power would be distributed in the secondary
25 maxima.

Various examples of multi-level diffractive lenses are shown in cross-sectional views in Figs. 3-5. Fig. 3 shows a diffractive lens having four levels; Fig. 4 shows a diffractive lens having two levels; and Fig. 5 shows a diffractive lens with eight levels.

30 In one embodiment of the present invention, a laser treatment apparatus and method utilizes plurality of diffractive lenses that are arranged in an array to produce

an output beam having a non-uniform energy profile. More specifically, the diffractive lens array is arranged in an optical path between a laser source and the treatment area, such that each lens in the array provides for an area of higher-fluence “hot spots” surrounded by lower-fluence regions of radiation. In a skin rejuvenation treatment, for example, the higher-energy areas provide sufficient heating to damage and shrink collagen in the “hot spots,” while the lower-intensity radiation regions outside of these hot spots overlap and combine to stimulate collagen regrowth over the entire treatment area.

In this embodiment, the laser source preferably produces a pulse of radiation having a wavelength between approximately 1.3 and 1.6 microns, preferably between 1.40 and 1.44 microns, and a pulse duration of between about 0.1 and 100 milliseconds, preferably between 1 and 5 milliseconds. The laser source can be an Nd:YAG laser, for example. An optical system carries the beam from the laser source to the treatment area. The diffractive lens array is preferably arranged at the distal end of the optical system, adjacent to the patient’s skin. The array comprises a plurality of separate diffractive lenses adjacent to one another. In general, there are 2000 or less lenses in an array, and preferably about 1800 lenses. Each lens is between about 150 and 450 microns in diameter, and is preferably about 250 microns in diameter. The entire array of diffractive lenses is generally about 7 to 10 mm in diameter. The array directs the input beam from the laser source (which is preferably also about 7-10 mm in diameter) into a plurality of higher-intensity “hot spots,” corresponding to the central portion of each individual lens in the array, and lower intensity regions surrounding each hot spot. The combined effect in the patient’s tissue is to produce a plurality of higher-intensity zones in the skin corresponding to the center of each diffractive lens surrounded by areas of lower-intensity radiation. This is shown in the treatment beam profile of Fig. 8. As can be seen in this graph, the entire treatment area receives at least a low level of treatment radiation, with certain spaced-apart portions receiving a higher dose of laser radiation. In the case of skin rejuvenation, for example, the laser energy penetrates deep into the collagen layer, where the collagen is heated to shrinkage temperatures in the “hot spots,” while the entire treatment area is treated to effect collagen

regeneration. In addition to skin rejuvenation treatment, the diffractive lens array can be optimized for use in other applications, such as treatment of acne and hair removal. A different beam profile from the diffractive lens array can be used for different applications.

- 5 The diffractive lens is considered to be irradiated by an average uniform fluence, F_{av} , determined by the laser fluence setting selected by the user. In general, the average fluence of the laser in this embodiment is less than about 10 J/cm², and is preferably about 9 J/cm². For purposes of illustration, each diffractive lens with diameter D is assumed to have a simplified design so that it produces a hot area with
- 10 diameter, d , assumed to have uniform fluence, F_1 , and a periphery having a uniform fluence, F_2 . The lens design is assumed to produce a fluence ratio, β , of the hot area versus the periphery, $\beta = F_1/F_2$. Under these simplifying assumptions, is it possible to derive a simple formula to approximate the hot area fluence, F_1 :

$$\frac{F_1}{F_{av}} = \frac{1}{\left(\frac{d}{D}\right)^2 + \frac{1}{\beta} \left[1 - \left(\frac{d}{D}\right)^2\right]} \quad (\text{Eq. 1})$$

- 15 Fig. 9 shows a plot of the relative hot area fluence factor, F_1/F_{av} , as a function of the relative diameter of the central hot area, d/D . As an example, if the diffractive lens is designed to have $\beta = 5$, with diameter $D = 250 \mu\text{m}$, hot area diameter $d = 100 \mu\text{m}$, and the laser is selected to have average fluence $F_{av} = 9 \text{ J/cm}^2$, then the hot area fluence is $F_1 = 3.05 \times 9 \text{ J/cm}^2 = 27.4 \text{ J/cm}^2$.

- 20 As a second example, if the diffractive lens is designed to have $\beta = 5$, with diameter $D = 350 \mu\text{m}$, hot area diameter $d = 200 \mu\text{m}$, and the laser is selected to have average fluence $F_{av} = 9 \text{ J/cm}^2$, then the hot area fluence is $F_1 = 2.17 \times 9 \text{ J/cm}^2 = 19.5 \text{ J/cm}^2$.

- Figs. 6 and 7 illustrate two exemplary embodiments of a diffractive lens
- 25 array according to the invention. In Fig. 6, the diffractive lenses are arranged in a

hexagonal pattern. In Fig. 7, the lenses are arranged in an elongated hexagonal pattern.

Fig. 10 shows the peak tissue temperature distribution for a portion of skin irradiated with a 1440 nm laser through a diffractive lens array. As can be seen from the graph, a first diffractive lens is centered at about 200 μm , and a second diffractive lens is centered at about 600 μm on the horizontal axis. As can be seen from this graph, there is an area of tissue about 200 μm wide centered on each of the diffractive lenses that is heated to relatively high peak temperatures (e.g., 70° C or higher). This high-temperature zone extends from essentially the surface of the skin to a depth of about 350 μm . As discussed above in connection with the fiber-bundle embodiment of Figs. 1A and 1B, these temperatures are sufficient to cause collagen shrinkage. Outside of these high-temperature treatment zones, the peak temperatures quickly drop off. For example, in the area between about 300 μm and 500 μm on the horizontal axis, the peak skin temperatures are generally between 35° C (or less) and 50° C, and are generally less than about 40° C. As previously discussed, these lower intensity zones provide collagen stimulation treatment.

Fig. 11 is a cross-sectional view of a tip 10 of a laser treatment apparatus having a diffractive lens array for providing an output beam having a non-uniform energy profile. The operator applies the tip 10 directly against the patient's skin 30. A laser source (not shown) is energized to produce an output beam 23, and the output beam is carried to the tip 10 by an optical fiber 20. The output beam 23 is emitted from the end of optical fiber 20, and is directed to diffractive lens array 61. Adjacent to the diffractive lens array 61 is an optical window 60 that directly contacts the patient's skin 30. The optical window 60 is similar to the optical window described in connection with Fig. 1, and functions as a spacer between the output end of the fiber bundle and the skin of the patient. The optical window 60 can be integral with the diffractive lens array 61. Preferably, the window is made of a good thermal conductive material, such as glass. The optical fiber 20, lens array 61, and optical window 60 are all enclosed in a tip housing 40, which is preferably a cylindrically-shaped housing. The tip housing 40 can be made of plastic. Outside the tip housing 40 is a cooling mechanism 11. Preferably, the cooling mechanism 11

comprises a conduit 50 that carries cooled air 51 from a cooled air source (not shown) to the tip 10 of the treatment apparatus. The conduit 50 preferably includes an outlet that is angled with respect to the tip housing 40, so that cooled air 51 is directed at the distal end of the tip housing 40 (*i.e.* where the tip 10 interfaces with the patient's skin 30). This arrangement provides effective cooling of the skin during laser treatment. Although the tip 10 and cooling mechanism 11 are shown here in connection with the diffractive lens array embodiment of Figs. 3-8, it will be understood that this design may also be employed with a laser apparatus having a fiber bundle, such as shown and described in connection with Figs. 1 and 2.

Fig. 12 shows an integrated laser and pulse light system for skin rejuvenation treatment, according to one aspect of the invention. As shown, the system 100 includes a housing 101 containing a laser source 103, preferably a solid-state laser, such as an Nd:YAG laser operating at about 1.4 microns wavelength and about 3 msec pulse width. Light from the laser source 103 is coupled into an optical fiber delivery system 20, which extends from the housing 101 to a first handpiece 105. The first handpiece 105 includes an optical system for producing a beam with a non-uniform energy profile, in accordance with any of the embodiments previously described herein. The handpiece 105 can include a tip 10 as previously described in connection with Fig. 11. The system can also employ a cooling system as described in connection with Fig. 11.

The integrated system 100 also includes a pulse light portion, that preferably includes a flashlamp light source 115. In a preferred embodiment, the flashlamp source comprises a Xenon flashlamp that produces treatment pulses having wavelengths between 560 and 950 nm and pulse widths between 5 and 35 milliseconds. The flashlamp 115 is located in a second handpiece 113 connected to the housing 101 by a high-voltage cable 111 that provides power to the flashlamp 115 from a high-voltage source 109 located within the housing 101. The pulse portion preferably also includes a water circulating system (not shown), as is conventionally known, for cooling the flashlamp. The pulse light system can also employ a cooling system as described in connection with Fig. 11. In one embodiment, an air cooler and conduit carry cold air to handpiece 115. The tip of

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handpiece 115 includes a sapphire window. The edge of the proximal side of the sapphire window (*i.e.* the side closest to the flashlamp source) is cooled by the cold air from the cooling system. The distal surface of the sapphire window contacts the patient's skin for treatment.

5 In operation, the second handpiece 113 is held proximate to the patient's skin, and the flashlamp 115 is energized to provide a treatment pulse. The spot size of the pulse light portion is generally larger than the laser portion, and is generally around 11 x 55 mm (or 6 cm²). The pulse light portion is thus able to treat large areas of the patient's skin in a relatively short time period. The maximum fluence of
10 the pulse light portion is typically around 20 J/cm².

The pulse light portion of the integrated system is well-suited to treat pigmented and certain vascular lesions. The pulse light portion effectively treats, for example, dischromia, a common condition associated with aging skin, as well as superficial pigmented lesions, veins, and the blush of rosacea associated with sun-
15 damaged skin. The laser portion of the system is effective for stimulation of collagen production and skin tightening, as previously discussed. The combination of laser treatment and pulse light treatment in an integrated system provides a complete and efficient system for facial rejuvenation treatment. The laser and pulse light system(s) are integrated in a common housing, and preferably use a common
20 control system 117, and can even use the same electronic drive circuit 119 for driving both the laser source 103 and the flashlamp source 115.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without
25 departing from the scope of the invention encompassed by the appended claims.

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CLAIMS

What is claimed is:

1. A method of treating human tissue, comprising:
generating an output beam from a laser source;
5 coupling the beam into an optical system that modifies the beam to provide a treatment beam having a non-uniform energy profile, the treatment beam comprised of a plurality of high-intensity zones surrounded by low-intensity zones within the treatment beam; and
directing the treatment beam to a target tissue area such that the high-
10 intensity zones heat select portions of the target tissue to a first temperature sufficient to shrink collagen, while the lower-intensity zones provide sufficient energy to the surrounding tissue to stimulate collagen production.
2. The method of Claim 1, wherein the treatment beam at the high-intensity zones heats select portions of the target tissue to a temperature of 70° C or
15 higher.
3. The method of Claim 1, wherein the laser source comprises an Nd:YAG laser.
4. The method of Claim 1, wherein the wavelength of the output beam is between about 1.3 microns and 1.6 microns.
- 20 5. The method of Claim 4, wherein the wavelength of the output beam is between about 1.40 and 1.44 microns.
6. The method of Claim 1, wherein the treatment beam at the target tissue area has a diameter between about 7 and 10 mm.

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7. The method of Claim 6, wherein the average fluence of the treatment beam at the target tissue area is less than about 10 J/cm².
8. The method of Claim 1, wherein the output beam has a pulse duration of between 0.1 and 100 milliseconds
- 5 9 The method of Claim 8, wherein the output beam has a pulse duration of between 1 and 5 milliseconds.
10. The method of Claim 1, wherein the optical system comprises a fiber bundle.
11. The method of Claim 10, wherein the fiber bundle comprises 1000 to 2000 fibers.
- 10 12. The method of Claim 10, wherein the optical system comprises a focusing lens for coupling the output beam into a proximal end of the fiber bundle, and an optical window between the distal end of the fiber bundle and the target tissue, the optical window permitting the beam emitted from each fiber in the bundle to diverge before it reaches the target skin so that each beam
15 partially overlaps with the beam(s) from adjacent fibers in the bundle.
13. The method of Claim 12, wherein the optical window is between 1 and 5 mm thick.
14. The method of Claim 10, wherein the average fluence of the treatment beam is less than about 10 J/cm².
- 20 15. The method of Claim 10, wherein the optical system comprises a transport fiber that carries the output pulse from the laser source to a handpiece containing the fiber bundle.

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16. The method of Claim 1, wherein the optical system comprises a diffractive lens array arranged in an optical path between a laser source and the treatment area, such that each lens in the array provides a high-intensity zone surrounded by a low intensity zone of radiation.
- 5 17. The method of Claim 16, wherein the diffractive lens array comprises about 2000 or less lenses in the array.
18. The method of Claim 17, wherein each lens is between about 150 and 450 microns in diameter.
19. The method of Claim 16, wherein the diffractive lens array is between 7 and
10 10 millimeters in diameter.
20. The method of Claim 16, wherein the average fluence of the laser output beam is less than about 10 J/cm².
21. The method of Claim 16, wherein the pulse duration of the output beam is between 0.1 and 100 milliseconds
- 15 22. The method of Claim 21, wherein the pulse duration of the output beam is between 1 and 5 milliseconds.
23. A treatment system, comprising:
a laser source that generates an output beam; and
an optical system that modifies the output beam to provide a
20 treatment beam having a non-uniform energy profile, the treatment beam being comprised of a plurality of high-intensity zones surrounded by low-intensity zones within the treatment beam, such that the high-intensity zones heat select portions of the target tissue to a first temperature to shrink

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collagen, while the lower-intensity zones provide sufficient energy to the surrounding tissue to stimulate collagen production.

24. The system of Claim 23, wherein the high-intensity zones heat the tissue to temperatures of 70° C or higher.
- 5 25. The system of Claim 23, wherein the laser source comprises an Nd:YAG laser.
26. The system of Claim 23, wherein the wavelength of the output beam is between about 1.3 microns and 1.6 microns.
27. The system of Claim 26, wherein the wavelength of the output beam is
10 between about 1.40 and 1.44 microns.
28. The system of Claim 23, wherein the treatment beam at the target tissue area has a diameter between about 7 and 10 mm.
29. The system of Claim 28, wherein the average fluence of the treatment beam at the target tissue area is less than about 10 J/cm².
- 15 30. The system of Claim 23, wherein the output beam has a pulse duration of between 0.1 and 100 milliseconds.
31. The system of Claim 30, wherein the output beam has a pulse duration of between 1 and 5 milliseconds.
32. The system of Claim 23, wherein the optical system comprises a fiber
20 bundle.

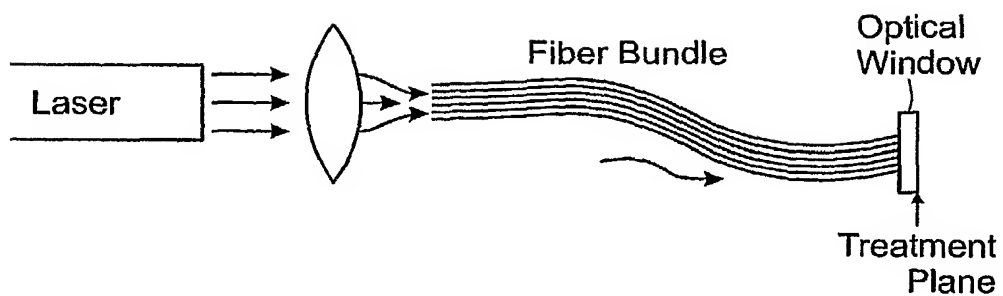
-20-

33. The system of Claim 32, wherein the fiber bundle comprises 1000 to 2000 fibers.
34. The system of Claim 32, wherein the optical system comprises a focusing lens for coupling the output beam into a proximal end of the fiber bundle, and an optical window between the distal end of the fiber bundle and the target tissue, the optical window permitting the beam emitted from each fiber in the bundle to diverge before it reaches the target skin so that each beam partially overlaps with the beam(s) from adjacent fibers in the bundle.
35. The system of Claim 34, wherein the optical window is between 1 and 5 mm thick.
36. The system of Claim 32, wherein the average fluence of the treatment beam is less than about 10 J/cm².
37. The system of Claim 32, wherein the optical system comprises a transport fiber that carries the output pulse from the laser source to a handpiece containing the fiber bundle.
38. The system of Claim 23, wherein the optical system comprises a diffractive lens array arranged in an optical path between a laser source and the treatment area, such that each lens in the array provides a high-intensity zone surrounded by a low intensity zone of radiation.
39. The system of Claim 38, wherein the diffractive lens array comprises about 2000 or less lenses in the array.
40. The system of Claim 38, wherein each lens is between about 150 and 450 microns in diameter.

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41. The system of Claim 38, wherein the diffractive lens array is between 7 and 10 millimeters in diameter.
42. The system of Claim 41, wherein the average fluence of the laser output beam is less than about 10 J/cm².
- 5 43. The system of Claim 38, wherein the output beam has a pulse duration of between 0.1 and 100 milliseconds.
44. The system of Claim 38, wherein the pulse duration of the output beam is between 1 and 5 milliseconds.
45. The system of Claim 23, further comprising:
10 a tip housing that contains the optical system, a distal end of the tip housing adapted to contact against the target tissue area of the patient; and
 a conduit that carries cooled air to the tip housing, the conduit comprising an outlet that is angled to direct cooled air onto the distal end of the tip housing.
- 15 46. A laser system, comprising:
 a laser source that generates an output beam;
 a fiber bundle comprising a plurality of individual fibers, the fiber bundle having a proximal end and a distal end;
 a focusing lens for coupling the output beam into a proximal end of
20 the fiber bundle; and
 an optical window at the distal end of the fiber bundle, the optical window permitting the beams emitted from each fiber in the bundle to diverge as the beam passes through the optical window so that each beam partially overlaps with the beam(s) from adjacent fibers in the bundle.

47. A laser system, comprising:
a laser source that generates an output beam having an average
fluence of less than about 10 J/cm²; and
a diffractive lens array arranged in an optical path between a laser
source and a treatment area, such that when the output beam passes through
the lens array, a non-uniform treatment beam is produced comprising a
plurality of high-intensity zones of radiation surrounded by a contiguous area
of lower-intensity radiation.
48. The system of Claim 23, further comprising a pulse light source integrated
with the laser source.
49. The system of Claim 48, wherein the pulse light source comprises a
flashlamp.
50. The system of Claim 49, wherein the flashlamp comprises a Xenon
flashlamp.
51. A treatment system, comprising:
a laser source that generates an output beam having an average
fluence of less than about 10 J/cm²;
a diffractive lens array arranged in an optical path between a laser
source and a treatment area, such that when the output beam passes through
the lens array, a non-uniform treatment beam is produced comprising a
plurality of high-intensity zones of radiation surrounded by a contiguous area
of lower-intensity radiation; and
a pulse light source integrated with the laser source.



Long Fiber Bundle with Optical Window in Contact with the Skin

FIG. 1A

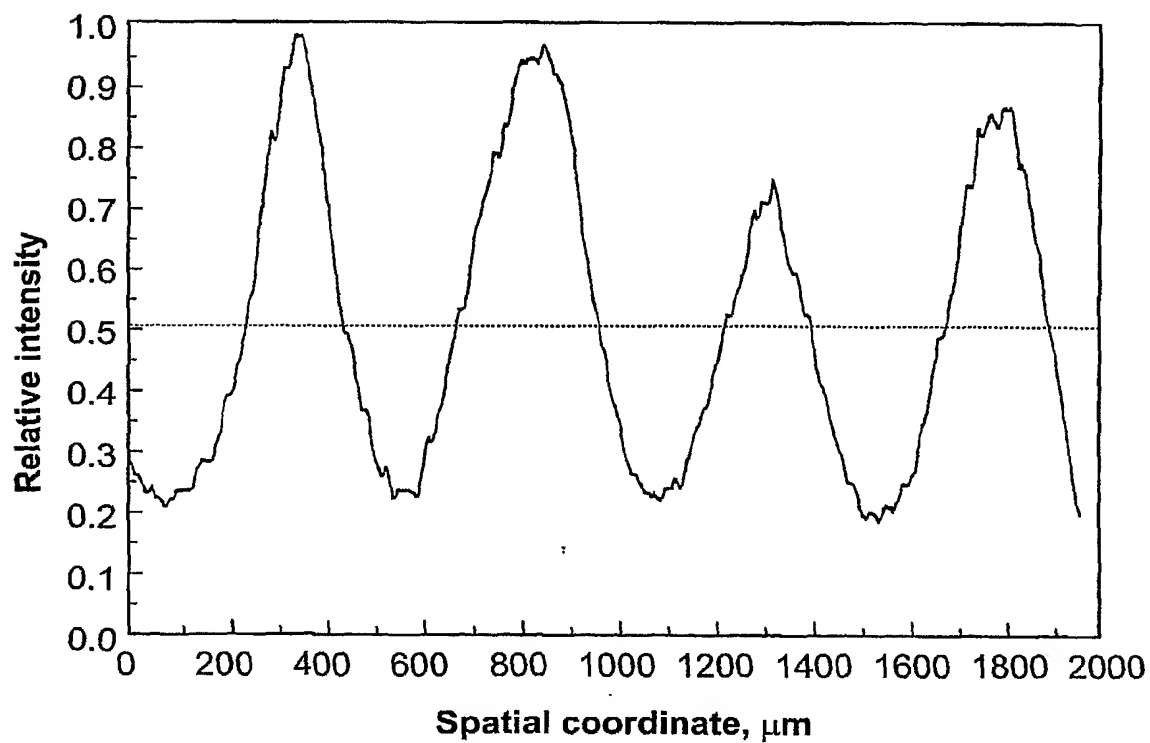


FIG. 1B

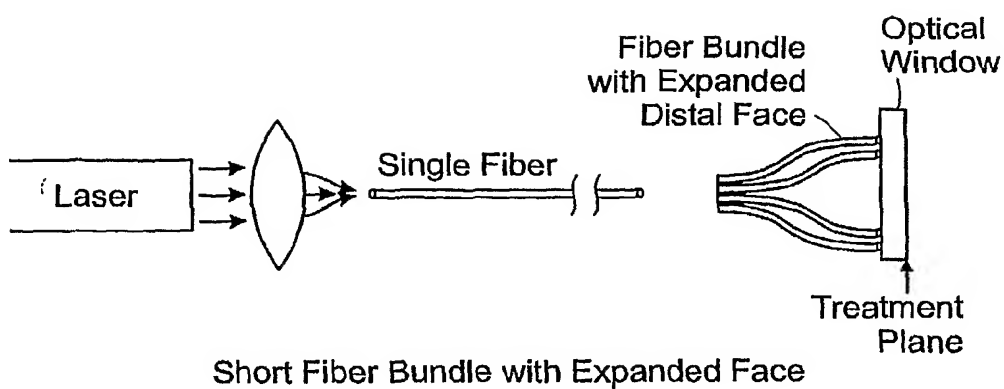
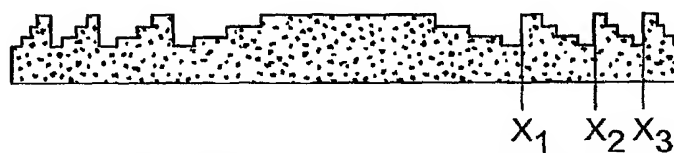
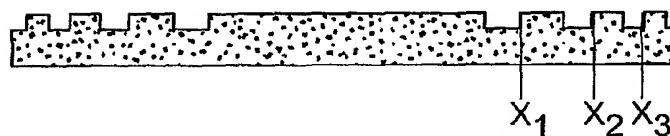


FIG. 2



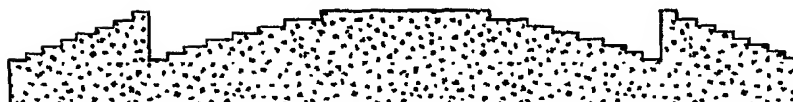
Diffractive Lens with Four Levels

FIG. 3



Diffractive Lens with Two Levels

FIG. 4



Diffractive Lens with Eight Levels

FIG. 5

Diffraction Lens Arrays Arranged in Hexagonal Shapes

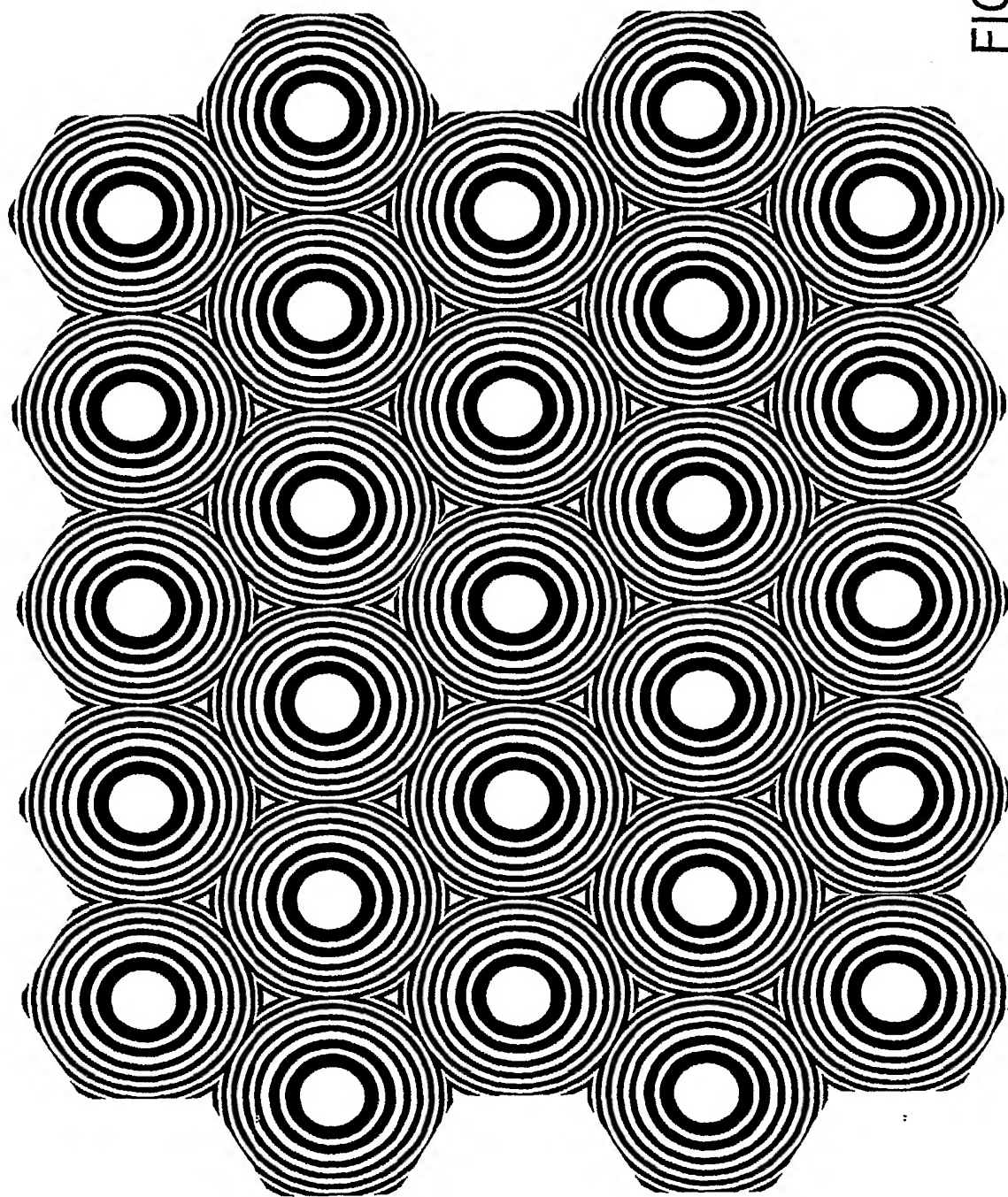


FIG. 6

Diffractive Lens Arrays Arranged in Elongated Hexagonal Shapes

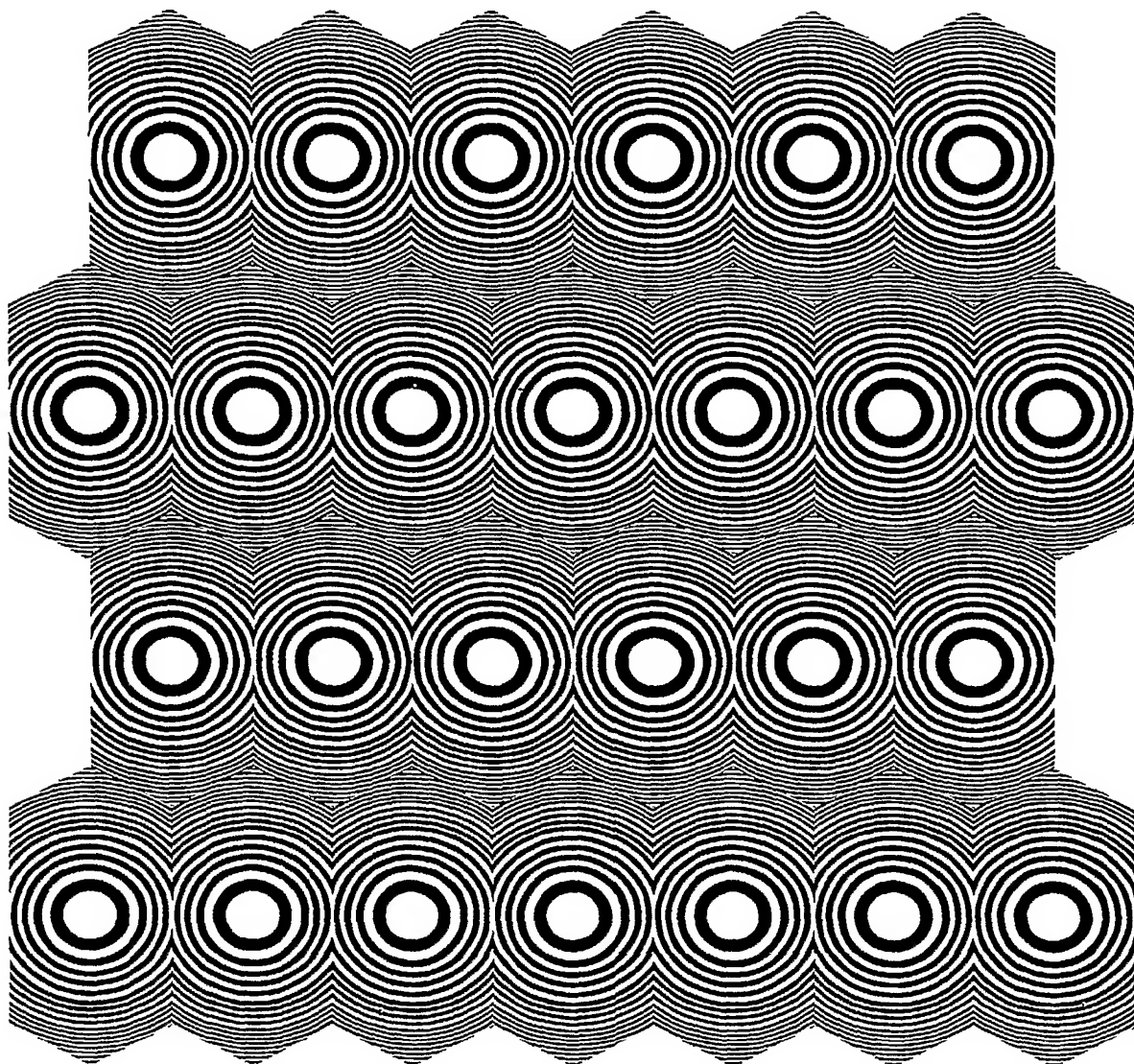


FIG. 7

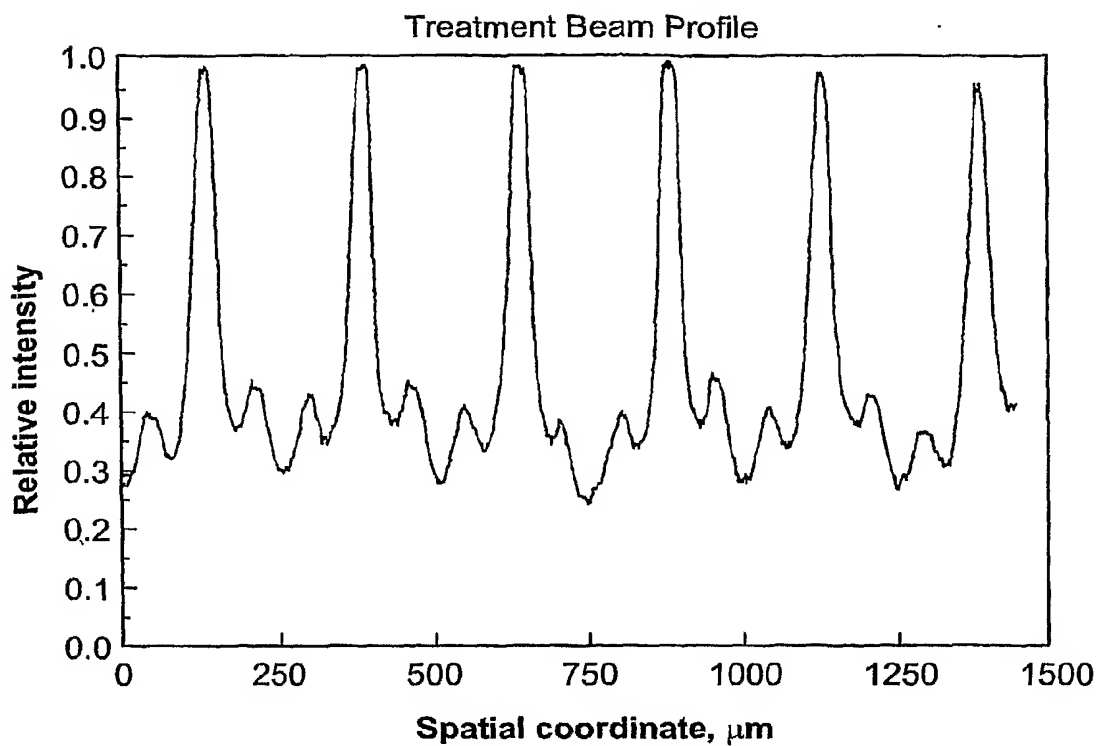


FIG. 8

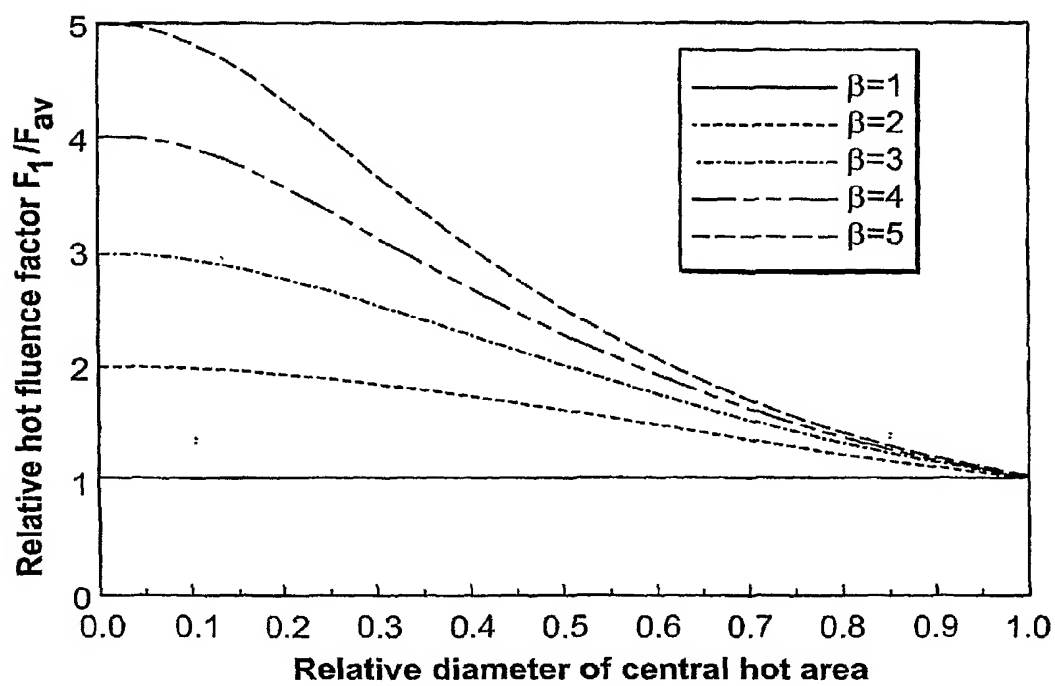
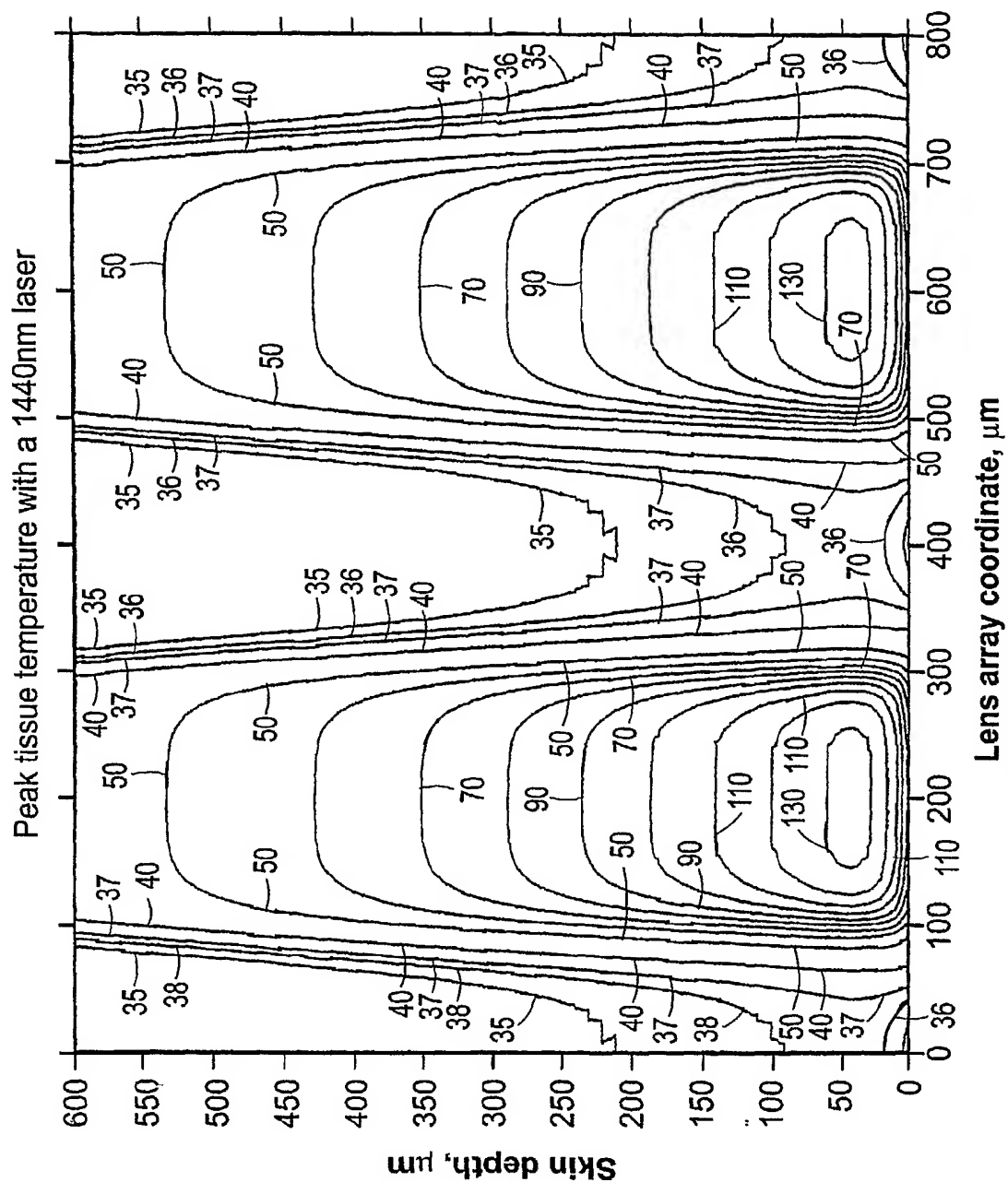


FIG. 9



Boundary in contact with a glass plate at 32°C, no precooling
200 μ m spot diameter, 22.3J/cm² in the dot, 7mJ/dot, 0.83J/cm² background, 7J/cm² HP fluence,
3ms pulse duration, 90% lens performance, 400 μ m lens spacing

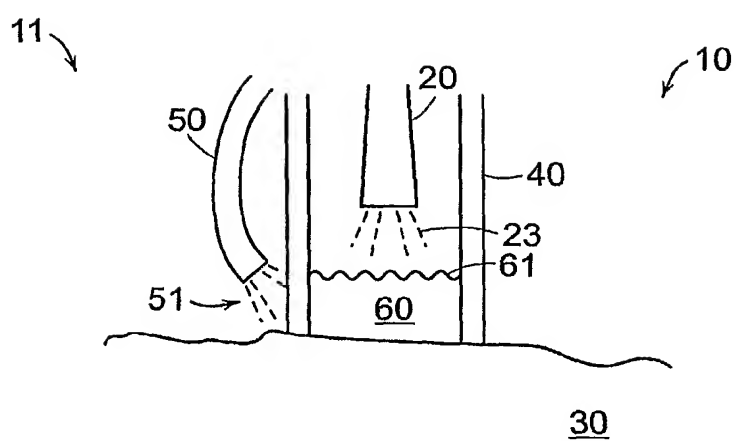


FIG. 11

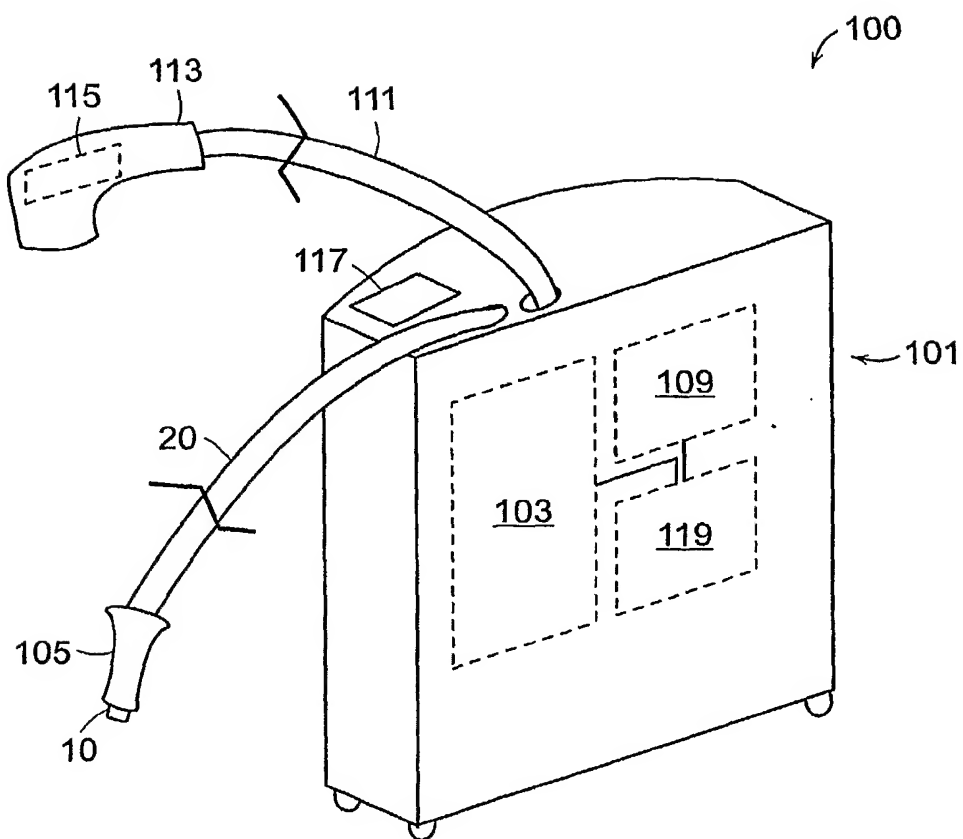


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/015180

A. CLASSIFICATION OF SUBJECT MATTER INV. A61N5/067 A61N5/06 A61B18/20		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61N A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/007003 A (RELIANT TECHNOLOGIES, INC; DEBENDICTIS, LEONARD, C; HERRON, G., SCOTT;) 27 January 2005 (2005-01-27) abstract; claims 12,28,29,32,36,52 paragraph [0094]	23-31, 38-45, 47-51
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A	US 2002/151878 A1 (SHIMMICK JOHN KARL ET AL) 17 October 2002 (2002-10-17) ----- -/--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *Z* document member of the same patent family		
Date of the actual completion of the international search 1 August 2006		Date of mailing of the international search report 11/08/2006
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Rodríguez Cossío, J

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/015180

Q(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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A	US 2004/143247 A1 (ANDERSON R. ROX ET AL) 22 July 2004 (2004-07-22) -----	
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/015180

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-22
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 23-31,38-45,47-51

treatment system comprising laser source and optical system
that modifies the output beam to provide an energy profile
with zones of higher and lower intensity by means of a
diffractive lens array

2. claims: 23-37,46

treatment system comprising laser source and optical system
that modifies the output beam to provide an energy profile
with zones of higher and lower intensity by means of a fiber
bundle

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/015180

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/015180

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(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 March 2007 (29.03.2007)

PCT

(10) International Publication Number
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- (22) **International Filing Date:**
15 September 2006 (15.09.2006)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
60/717,490 15 September 2005 (15.09.2005) US
- (71) **Applicant (for all designated States except US):** PALOMAR MEDICAL TECHNOLOGIES, INC. [US/US]; 82 Cambridge Street, Burlington, MA 01803 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** ALTSHULER, Gregory [US/US]; 17 Cerulean Way, Lincoln, MA 01773 (US). WANG, Guangming [CN/US]; 39 Genetti Circle, Bedford, MA 01730 (US). ZENZIE, Henry [US/US]; 14 Whiting Road, Dover, MA 02030 (US).
- (74) **Agents:** MOLLAAGHABABA, Reza et al.; Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604 (US).

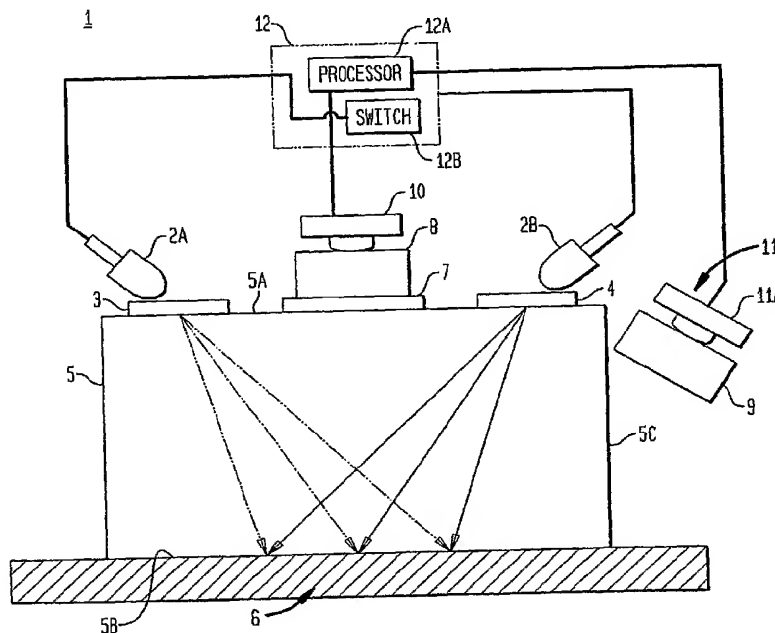
(81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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[Continued on next page]

(54) **Title:** SKIN OPTICAL CHARACTERIZATION DEVICE



(57) **Abstract:** The present invention is generally directed to dermatological devices and methods in which one or more skin characteristics, such as the melanin index, are determined by analyzing radiation backscattered from a skin region illuminated by at least one, and preferably, two or more wavelengths, e.g., in a range of about 600 nm to about 900 nm. In many embodiments, the radiation is coupled to the skin via a waveguide, and an optical sensor is employed to ascertain contact between the waveguide (e.g., a waveguide surface adapted for contact with the skin) and the skin.

WO 2007/035444 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SKIN OPTICAL CHARACTERIZATION DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application
5 Serial No. 60/717,490 filed on September 15, 2005, which is herein incorporated
by reference in its entirety.

BACKGROUND

The present invention relates generally to diagnostic and therapeutic
10 dermatological devices and methods that measure physical characteristics of
tissue, such as, the skin.

Dermatological devices are used to improve a variety of skin conditions,
such as removal of unwanted hair, skin rejuvenation, removal of vascular lesions,
15 acne treatment, treatment of cellulite, pigmented lesions and psoriasis, tattoo
removal, treatment of skin and other cancers, etc. Many of these devices typically
target a chromophore in the tissue of the subject under treatment. Depending on
the procedure, such a chromophore may be, for example, melanin, hemoglobin,
lipid, water, or pigment of a tattoo.

20
Optimal use of these devices depends, at least in part, on accurate
identification of the subject's skin pigmentation so that proper treatment
parameters can be used. However, commonly used methods of skin typing are
not generally based on actual measurements of the chromophores of interest, such
25 as the amount of melanin in the skin. For example, the commonly used
Fitzpatrick skin type scale, which ranges from very fair (skin type I) to very dark
(skin type VI), is based solely on a person's complexion and response to sun
exposure. In addition, such conventional skin typing methods do not take into
account variations in the concentration of a chromophore in different parts of an
30 individual's skin. For example, although different parts of an individual's skin
can exhibit different melanin concentrations, the Fitzpatrick scale provides only a
single skin type for that individual. As such, the use of such conventional skin
typing methods may result in complications during treatment, such as burns,
scars, or ineffective treatment.

Therefore, a need exists for dermatological and other devices and methods that can accurately and efficiently determine physical characteristics of a person's skin, such as, for example, skin melanin optical density (MOD), blood content, collagen content, and/or hydration. In addition, improved safety mechanisms are needed for dermatological devices so that they can be used for non-professional uses, such as home use.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides a dermatological device for determining a physical characteristic of a portion of tissue that comprises a radiation source assembly configured to generate radiation having at least a first wavelength and a waveguide coupled to that source assembly for directing the radiation from the source to the tissue portion, where the waveguide has a surface configured to irradiate the tissue portion with the radiation. The device further includes a detector coupled to the waveguide and configured to detect radiation from the source, where the detector generates signals indicative of the level of radiation detected. A processor in communication with the detector processes the signals and calculates a physical characteristic of the tissue region. The detector can be configured to detect the radiation from the source after the portion of the tissue has been irradiated with the radiation from the source.

In a related aspect, the skin characteristic can be, e.g., any of melanin index, collagen content, diffusion or erythema measurement.

In another aspect, the radiation source assembly can include two or more radiation sources. For example, the first radiation source can produce radiation having a first (or first wavelength band) wavelength and a second radiation source can produce radiation having a second wavelength (or second wavelength band). Alternatively, the radiation source assembly can include a single radiation source. The radiation source can produce radiation of more than one wavelength (i.e., radiation of a first wavelength and also radiation of a second wavelength), or radiation source assembly can be configured to generate radiation having two or more, or three or more wavelengths. The first and/or second wavelength can be

selected from a range of about 350 nm to about 1200 nm, or from a range of about 600 nm to about 900 nm. In some embodiments, the radiation source assembly can include at least one of a light emitting diode (LED), a bi-color LED, a tunable radiation source, and/or a laser radiation source. The term "wavelength" as used
5 herein is not necessarily limited to monochromatic light but rather can also define a line or band of wavelengths, depending upon the nature of the light source.

In another aspect, the device can further comprise a contact sensor indicating whether the surface of the optical waveguide is in contact with the skin.
10 By way of example, the contact sensor can be configured to detect a level of the radiation at a wavelength generated by the source. In some embodiments wherein the radiation source assembly is configured to generate radiation having two or more wavelengths, the contact sensor can be configured to detect a level of the radiation at two or more of those wavelengths.

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In a related aspect, in the above device, the contact sensor can be configured to send a signal to the processor indicating that the surface of the waveguide is not in contact with the tissue. For example, the contact sensor can send a signal when the contact sensor detects that the detected radiation level is
20 below or above a threshold. The contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to totally internally reflect the radiation along that boundary when the surface is not in contact with the tissue. Alternatively, the contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to not
25 totally internally reflect the radiation along that boundary when the surface is not in contact with the tissue.

In another aspect, the contact sensor can be configured to send a signal to the processor indicating that the surface of the waveguide is in contact with the
30 tissue. For example, the contact sensor can detect that the detected radiation level is above or below a threshold. The contact sensor can be optically coupled to the waveguide along a boundary, wherein the waveguide is configured to not totally internally reflect the radiation along that boundary when the surface is in contact with the tissue. Alternatively, the contact sensor can be optically coupled to the

waveguide along a boundary, wherein the waveguide is configured to totally internally reflect the radiation along that boundary when the surface is in contact with the tissue.

5 In another aspect, the device can further comprise two polarizers, one of which can be configured to filter radiation of a first polarity from the radiation source assembly and the other can be configured to filter radiation of a second polarity entering the contact sensor and/or entering the detector. The device can include a filter disposed between the contact sensor and the waveguide and/or
10 between the waveguide and the detector.

 In another aspect, the device can further comprise a controller coupled to the radiation source assembly. The controller can be configured to activate the radiation source assembly to produce radiation of different wavelengths at
15 different times.

 In another aspect, the waveguide can be formed of a material having an index of refraction in a range of about 1.4 to about 2.5. In some embodiments, the waveguide is an optical fiber. The device can further include at least one
20 additional waveguide coupled to the source assembly. In some cases, that additional waveguide can be an optical fiber.

 In another aspect, the invention discloses a dermatological device for determining a physical characteristic of a portion of tissue that comprises a
25 radiation source assembly configured to generate radiation having first and second wavelengths, and a waveguide coupled to the source assembly for directing the radiation from the source to a portion of the tissue, and having a surface configured to irradiate that tissue portion with the radiation. The waveguide surface can be adapted for contact with the tissue and can inhibit transmission of
30 radiation in absence of skin contact by total internal reflection of radiation reflected by a sidewall thereto. The device can further include a detector coupled to the waveguide and configured to detect radiation from the source, wherein the detector can generate signals indicative of the level of radiation detected. The detector can be configured to detect the radiation from the source after the portion

of the tissue has been irradiated with the radiation from the source. A processor in communication with the detector can process the signals and calculate a physical characteristic of the tissue portion (e.g., a skin portion). In other words, the processor can determine a tissue (e.g., skin) characteristic based on the
5 detector output.

In a related aspect, in the above device, a contact sensor optically coupled to the waveguide along a boundary can be configured to detect a level of the radiation transmitted through that boundary to determine whether said waveguide
10 surface is in contact with the tissue..

In a related aspect, the first and second wavelengths can be in a range of about 300 nm to about 1200 nm, about 600 nm to about 900 nm, or about 630 nm to about 730 nm. For example, the first wavelength can be approximately 645
15 nm, or approximately 700 nm. In some embodiments, the first wavelength is approximately 645 nm and the second wavelength is approximately 700 nm.

In another related aspect, the device can further comprise a feedback mechanism in communication with the sensor and the source, wherein the
20 feedback mechanism is capable of inhibiting activation of the source when the sensor indicates lack of optical contact between the waveguide and the source, and is capable of activating the source when the sensor indicates optical contact.

In another aspect, the invention provides a dermatological device with at
25 least one radiation source, a waveguide optically coupled to the radiation source to transmit radiation from the source to the skin, the waveguide having two opposed surfaces and a sidewall extending between the surfaces. The device can further include a detector coupled to the waveguide to detect at least a portion of radiation backscattered from a skin region illuminated by the source radiation, and
30 an optical contact sensor optically coupled to the sidewall, the sensor determining whether the waveguide is in contact with the skin based on detection of backscattered radiation leaking through the sidewall.

In yet another aspect, a dermatological device is disclosed comprising a radiation source assembly, a first waveguide having a proximal end adapted to receive radiation from the radiation source assembly and a distal end adapted to transmit radiation to a tissue, a second waveguide having a distal end adapted to receive backscattered radiation from the first waveguide and a proximal end adapted to transmit the backscattered radiation. The device can further include a detector optically coupled to the second waveguide and configured to measure a physical characteristic of the tissue; and a processor electrically coupled to the detector and configured to receive a signal from the detector corresponding to the backscattered radiation. The processor is configured to determine a physical characteristic of the tissue based on the backscattered radiation that is detected. The device can further include a means for coupling the backscattered radiation exiting from the proximal end to the detector, such as a beamsplitter. The radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 350 nm to about 1200 nm, or about 600 nm to about 900 nm. The device can further comprise additional waveguides, such as optical fibers.

In another aspect, the invention provides a dermatological device that comprises at least one source of radiation, an optical fiber receiving radiation from the source at a proximal end and applying the radiation to a skin region at a distal end, another optical fiber coupled at a distal end to skin at another region separated from the illuminated region by a skin segment so as to receive at least a portion of the applied radiation after transmission through that segment, a detector optically coupled to a proximal end of the another optical fiber to detect at least a portion of the transmitted radiation received by that fiber, the detector generating a signal indicative of an intensity of the received radiation, and a processor operating on the detector signal to determine a skin characteristic.

In another aspect, a method of determining a characteristic of tissue is disclosed that comprises the steps of applying radiation of first and second wavelengths from a waveguide to the tissue; detecting at least a portion of radiation of the first and second wavelengths backscattered from the tissue; generating at least one signal indicative of an intensity of the backscattered

radiation, and processing the at least one signal to calculate a characteristic of the skin region. The step of applying radiation can further include applying radiation at a plurality of wavelengths selected from a range of about 350 nm to about 1200 nm, or in a range of about 600 nm to about 900 nm, to the skin. In addition,
5 optical contact between the waveguide and the skin region can be detected. Contact of the waveguide with the tissue can be sensed by detecting a level of the backscattered radiation. The method can further include reducing ambient radiation to prevent its detection by the detector. In some embodiments, the method further can include reducing radiation having a first polarity prior to
10 detection; and detecting radiation having a second polarity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A is a schematic side view of a dermatological device in accordance with one embodiment of the invention;
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FIGURE 1B schematically shows that in the absence of contact between a waveguide of the device of FIGURE 1A and the skin, a substantial number of radiation rays backscattered from the skin into the waveguide are totally internally reflected at the waveguide's sidewall to which an optical sensor is optically
20 coupled, thus resulting in a low detection signal by the sensor;

FIGURE 1C schematically shows that in the presence of contact between the waveguide of device of FIGURE 1A and the skin, a substantial number of radiation rays backscattered from the skin into the waveguide to be incident on a
25 sidewall of the waveguide to which an optical sensor is coupled are transmitted through the sidewall to reach the sensor, thus resulting a sensor signal above a threshold that indicates contact;

FIGURE 1D schematically shows that the detector of an optical sensor
30 coupled to a sidewall of a waveguide of the device of FIGURE 1A is positioned relative to the sidewall such that a central ray corresponding to the detector's viewing solid angle makes an angle ϕ relative to the sidewall selected to ensure that in the absence of contact between the waveguide and the skin, the radiation rays backscattered from the skin into the waveguide are substantially inhibited

from reaching the detector and, in presence of contact, some of those rays exit the sidewall to reach the detector;

FIGURE 1E schematically depicts a skin portion comprising an epidermis
5 layer, a dermis layer and an epidermis/dermis junction exhibiting a high concentration of melanin;

FIGURE 1F is a schematic diagram of rays of radiation entering a
waveguide from the air at various angles;
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FIGURE 1G is a schematic diagram of rays of radiation entering a
waveguide from skin tissue at various angles;

FIGURE 2 depicts the emission spectra associated with two exemplary
15 LEDs suitable for use in some embodiments of the invention;

FIGURE 3 depicts trigger signals applied to the LEDs forming radiation
sources in an embodiment of the invention as well as the backscattered signals
detected for illumination of a skin portion with radiation generated by those
20 LEDs;

FIGURE 4 shows the signal sensitivity of an exemplary, illustrative device
according to an embodiment of the invention for measuring the melanin index as
a function of tilt angle relative to the skin under observation;
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FIGURE 5 shows the signal sensitivity of an exemplary, illustrative device
according to an embodiment of the invention for measuring the melanin index as
a function of the thickness of an air gap between a surface of a device adapted for
contact with the skin and a skin portion under observation;
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FIGURE 6 is a schematic side view of a dermatological device according
to another embodiment of the invention that employs a single radiation source
capable of generating radiation at two or more wavelengths in a wavelength range
of interest;

FIGURE 7A schematically depicts a dermatological device in accordance with another embodiment of the invention that utilizes a waveguide having a reflective sidewall for coupling radiation from a source into the skin;

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FIGURE 7B schematically shows that the reflective sidewall of the waveguide of the device of FIGURE 7A directs radiation received from the source to a surface of the waveguide adapted for contact with the skin such that in the absence of contact, the radiation is totally internally reflected from that contact surface;

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FIGURE 8A is a schematic side view of a dermatological device according to another embodiment of the invention that includes two radiation sources capable of generating radiation at different wavelengths and a waveguide having reflective sidewalls for reflecting radiation from those sources to the skin;

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FIGURE 8B is a schematic side view of a dermatological device in accordance with another embodiment of the invention that utilizes two radiation source whose radiation is reflected to the skin via reflective sidewalls of a waveguide and further includes two detectors for detecting radiation backscattered from the illuminated skin;

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FIGURE 9 schematically depicts a dermatological device in accordance with another embodiment of the invention that utilizes a radiation source to couple radiation via a prism to the skin at one location and utilizes a detector optically coupled to the skin at another location to collect at least some of the radiation transmitted through the skin for measuring a characteristic of the skin, such as the melanin optical density;

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FIGURE 10 schematically depicts the use of the device of FIGURE 9 placed above and detecting the iris of a human eye;

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FIGURE 11A schematically depicts a dermatological device in accordance with another embodiment of the invention that employs optical fibers for coupling radiation into the skin and for collecting radiation backscattered from the skin;

5 FIGURE 11B schematically depicts another embodiment of a dermatological device according to the teachings of the invention that employs one or more optical fibers for coupling radiation into the skin and an annular waveguide for collecting radiation that is backscattered from the skin;

10 FIGURE 11C is a perspective schematic view of an exemplary annular waveguide suitable for use in the device of FIGURE 11B;

 FIGURE 11D is a perspective schematic view of an annular waveguide suitable for use in the device of FIGURE 11B, which comprises a plurality of
15 optical fibers disposed in an annular enclosure;

 FIGURE 11E is a schematic top view of a surface area of the skin illuminated by a radiation source of the device of FIGURE 11B as well as an area coupled to the annular waveguide of that device through which backscattered
20 radiation is collected;

 FIGURE 12 is a schematic side view of a device in accordance with another embodiment of the invention that employs an optical fiber for transmitting radiation received from a source at a proximal end thereof to the skin
25 via its distal end;

 FIGURE 13 schematically depicts another embodiment of a dermatological device according to the teachings of the invention that includes an optical fiber having a split end to provide an input port for receiving radiation
30 from a source and output port for coupling backscattered radiation collected at its distal end to a detectors;

FIGURE 14 schematically depicts a dermatological device according to an embodiment of the invention having a treatment module and a diagnostic module, which is constructed in accordance with the teachings of the invention; and

5 FIGURE 15 schematically depicts a dermatological device according to an embodiment of the invention designed to provide both diagnostic and treatment capabilities in a compact enclosure.

DETAILED DESCRIPTION

10 The present invention relates generally to diagnostic and/or therapeutic dermatological and other devices, as well as diagnostic and therapeutic methods, that determine one or more characteristics of the skin by analyzing radiation scattered by the skin in response to its illumination at at least one wavelength, and more preferably, at two or more wavelengths. In other aspects, the invention
15 provides optical sensors for determining whether an optical element, such as a waveguide or treatment window through which radiation from a device is transmitted to the skin, is in contact with the skin.

FIGURE 1A schematically depicts a cross-sectional view of an exemplary
20 dermatological device 1 in accordance with one embodiment of the invention that measures a physical property of tissue, the melanin optical density (“MOD”) of human skin in this particular embodiment. Device 1 includes two light sources 2A and 2B that generate radiation having different wavelengths selected to be sufficiently separate to provide two independent measures of the physical
25 characteristic. Depending on the application, various wavelengths can be used. In this case, for the measurement of MOD, many different wavelengths can be selected, but the wavelengths preferably are in a range of about 600 nm to about 900 nm, though wavelengths in other ranges can also be employed. (The terms “light” and “radiation” are herein used interchangeably to refer to electromagnetic
30 radiation within a desired spectral range. Unless otherwise specified, these terms are used as examples, and it should be understood that other forms of radiant energy can be used depending on the application, including acoustic energy, ultrasound, microwaves, infrared, visible light and other electromagnetic radiation.)

Generally, the separation of the wavelengths is selected so as to elicit a sufficient differential response at those wavelengths from a skin chromophore (e.g., melanin) so as to allow accurate measurements of that chromophore's concentration in the skin. By way of example, in this embodiment, source 2A generates radiation at a wavelength of about 645 nm, while source 2B generates radiation at a wavelength of about 700 nm. This choice of the wavelengths is particularly suited for measuring the skin melanin content, as it provides adequate differential response from melanin while minimizing optical interference from other skin components, such as blood or water.

A variety of coherent or incoherent radiation sources can be utilized as sources 2A and 2B. For example, in some embodiments, the sources 2A and 2B include light emitting diodes (LEDs) while in others, they can include laser diodes, lamps, etc. In still other embodiments, a single source can be used to produce both wavelengths of light by, for example, passing light from an incoherent source through one or more filters. Similarly, a single source could be used to provide radiation across one or more bands of radiation, while the desired wavelengths within the band are detected using sensors sensitive to those wavelengths.

The use of LEDs in this exemplary embodiment provides a number of advantages. For example, LEDs are typically low cost, compact and reliable radiation sources. Further, their light output can be controlled and modulated precisely. In addition, the profiles of their output radiation beams can be controlled, e.g., by utilizing molded lenses. It should, however, be understood that any other suitable radiation source can also be employed.

The light sources 2A and 2B are optically coupled to a waveguide 5 via a top surface 5A thereof such that at least a portion of the light generated by each source enters the waveguide for transmission to a subject's skin. Waveguides are well known in the art of optics, and generally refer to any optically transmissive medium that provides an optical path from a first location to a second location through the medium. As discussed in more detail below, the radiation entering

the waveguide is transmitted by the waveguide to a surface 5B thereof through which, upon contact of that surface with the skin, the radiation is transmitted to a skin region 6. A portion of the radiation illuminating the skin is specularly reflected by the skin surface, and another portion enters the skin.

5

As the skin is a turbid medium, the radiation entering the skin undergoes multiple scattering and/or reflection events, which result in re-entry of some of the radiation back into the waveguide (that is, some of the radiation is backscattered into the waveguide). The waveguide 5 can advantageously function similarly to an optical integrating sphere to allow a substantially uniform illumination of a skin segment of interest, and can facilitate coupling of the backscattered radiation to a detector 10. The detector 10 is optically coupled to the surface 5A of the waveguide to receive at least a portion of the backscattered radiation that is coupled from the skin into the waveguide, via the waveguide's surface 5B. At least a portion of the backscattered radiation is coupled out of the waveguide through the surface 5A to be detected by the detector. A variety of optical radiation detectors known in the art can be employed. An example of such a detector includes a commercially available detector marketed by Hamatsu as serial number 56865-01.

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As such, the waveguide can allow repeatable optical coupling between the device and the skin. As discussed in more detail below, poor coupling between the device and the skin can lead to inaccurate measurements due to dramatic changes in light coupling, transmission and diffusion. Furthermore, in device 1, the waveguide medium is a substance, in this case, sapphire or other suitable medium, such as fused silica or glass, that has an index of refraction sufficiently different than air to, as discussed in greater detail below, utilize the concept of total internal reflection to achieve the desired measurement of MOD. (However, as will be evident in additional embodiments described below, other media, including substances having an index of refraction close to that of air or even air itself, may be used as a waveguide. For example, a hollow reflective tube containing a fluid such as air or configured to secure a liquid, could be used as a waveguide in some embodiments.)

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Device 1 further includes polarizers 3 and 4, which have parallel polarization axes which are placed between the light sources 2A and 2B, respectively, and the surface 5A of the waveguide 5. Another polarizer 7, having a polarization axis perpendicular to that associated with polarizers 3 and 4, is placed between detector 10 and the surface 5A of the waveguide 5. The purpose of the polarizers 3, 4 and 7 is to remove light reflected from the surface of the tissue and other surfaces and that does not, therefore, penetrate into the tissue. This arrangement of polarizers ensures that the radiation that is specularly reflected from various interfaces (e.g., waveguide/air, waveguide/skin, air/skin, or waveguide/lotion, air/lotion (in cases where lotion is applied to the skin)) is substantially inhibited from reaching the detector 10. Such specularly reflected radiation has the same (or at least substantially the same) polarization as that of the polarized radiation from the sources, and hence is blocked by the orthogonal polarizer coupled to the detector. The use of this arrangement of polarizers is particularly advantageous in preventing the radiation that is specularly reflected from the skin surface from reaching the detector. The specularly reflected radiation does not penetrate the skin and hence it typically does not contain any information regarding the skin pigment of interest. Its blockage from the detector 10 increases the accuracy of the measurement. In contrast, the information regarding the skin pigment of interest is carried mostly by the light that is diffusely backscattered by the dermis layer of the skin. As this diffusely scattered light exhibits random polarization, a portion of the light having the opposite polarization from the specularly reflected light can pass through the polarizer 7 to be detected by the detector 10. Thus, the light that reaches detector 10 is predominately light that provides information about the physical characteristic being measured, in this case the MOD of the tissue.

In addition, device 1 contains a spectral filter 8 between polarizer 7 and detector 10. This filter passes the desired wavelengths emitted by sources 2A and 2B, but filters out other sources of radiation noise (e.g., ambient light and radiation from the treatment source), thereby enhancing the measurement sensitivity of the device.

With continued reference to FIGURE 1A, the device 1 further includes an optical contact sensor 11, comprising a radiation detector 11A and a filter 9, that is optically coupled on one side to detector 11a and to the waveguide 5 via a sidewall 5C thereof (which extends between the surfaces 5A and 5B), to detect
5 contact between the waveguide (and more particularly between the surface 5B of the waveguide through which the radiation is transmitted to the skin) and the skin. The terms "contact" and "optical contact," as used herein, refer not only to physical contact but also sufficient proximity between a surface of the waveguide and the skin that would result in detection of a signal by the sensor above a
10 predefined threshold.

In particular, the detector 11 detects a portion of the radiation that enters the waveguide through the surface 5B and exits the waveguide through the sidewall 5C. When the optical coupling between the surface 5B and the skin
15 surface is poor (e.g., when a substantial air gap is present between that surface and the skin) the amount of radiation that is leaked from sidewall 5C is low, and, thus, detector 11 detects a low signal. When the optical coupling between the surface 5B and the skin surface is good (e.g., when little or no gap exists between surface 5B and tissue 6 or when full contact is achieved between the tissue 6 and
20 the surface 5B) the amount of radiation that is leaked from sidewall 5C is substantially increased, and, thus, detector 11 detects a high signal.

The difference in the two signals is due to the total internal reflection of the light due to the difference in the indices of refraction of the waveguide and the
25 air. The waveguide has an index of refraction that is significantly greater than that of the air, approximately 1.45 to 1 respectively. Thus, in operation, the bulk of the radiation emitted from sources 2A and 2B will exit the waveguide via surface 5B, and only a small portion will be reflected internally, and only a small portion of that reflected radiation will exit sidewall 5C. When the surface 5B is
30 oriented toward the tissue 6, some of the emitted light will be reflected back to the device. The differences in the indexes of refraction, however, cause the light to refract upon reentry into waveguide 5 at angles that subsequently cause substantially all of the light to be totally internally reflected, such that essentially none of the light exits surface 5c.

When the device is touching the tissue, substantially more light reenters the waveguide 5 and passes through surface 5C. Thus, detector 11 then detects a significantly greater amount of light, thereby indicating that contact has been made (or that the device is positioned sufficient close to obtain a reading of MOD). The detector 11A of the sensor 11 indicates the presence of optical contact between the waveguide and the skin when its detection signal exceeds a pre-defined threshold, and it indicates the absence (or poor) optical contact between the waveguide and the skin when the detection signal is less than that threshold.

The principle is illustrated in FIGURES 1F and 1G. Figure 1F shows the condition where the waveguide 5 is not in contact with the tissue. Thus, the medium that the rays of light a, b and c travel through prior to entering the waveguide is air, which has an index of refraction of approximately one ($n=1$), while the index of refraction of the waveguide is approximately 1.45. Thus, as shown in greater mathematical detail below, any ray traveling within the waveguide that strikes a waveguide/air boundary at an angle that is larger than 43.6 degrees (the critical angle, which is measured relative to a normal line extending from surface 5c) will be totally internally reflected. However, as illustrated in FIGURE 1F, all radiation that reenters the waveguide will be refracted to an angle that is larger than the critical angle relative to surface 5c. For example, ray a, which is normal to the air/waveguide boundary, travels in a straight line and parallel to surface 5c. Ray b strikes the air/waveguide boundary at an angle of incidence of 46.4 degrees from the normal relative to surface 5b, but is refracted to a steeper angle relative to surface 5c and is totally internally reflected. Similarly, ray c, which is nearly parallel to the air/waveguide boundary, is also refracted: to an angle slightly greater than the critical angle of 43.6 degrees relative to a line normal to surface 5c. Thus, ray c is also totally internally reflected.

In the case where the waveguide 5 is in contact with the tissue 6, as shown in FIGURE 1G, any light that strikes the tissue/waveguide boundary at an angle of incidence greater than θ_c (46.4 degrees) will not be totally internally reflected at

the surface 5c. In this example, the indices of refraction of the tissue and the waveguide are approximately the same ($n=1.45$). Therefore, the light will not refract significantly, and will continue to travel in an essentially straight line. Thus, any radiation having an angle of incidence greater than approximately angle z will not be totally internally reflected. As shown in FIG. 1G, rays c and d are not totally internally reflected. Ray b, which has an angle of incidence on surface 5c at the critical angle γ (43.6 degrees), is totally internally reflected. Any ray incident at a smaller angle than 43.6 degrees will not be totally internally reflected. Any ray incident at a larger angle than 43.6 degrees will be totally internally reflected.

Of course, many other embodiments are possible, including, without limitation, embodiments where the reverse is true, *i.e.*, the light is totally internally reflected until contact is made, thus causing the level of light detected to drop significantly when contact is made. Thus, contact may be signaled when the light level drops below a defined threshold. Additionally, although it is preferable to use a waveguide having an index of refraction that is matched or nearly matched to that of the tissue, it is not essential. Alternate embodiments can be designed having indices of refraction that are not matched. For embodiments used on the surface of the skin, it is preferable, though not essential, to use a lotion to facilitate the transfer of radiation from sources 2A and 2B to the skin, and even more preferable to use a lotion with an index of refraction that is matched to or nearly matched to the refractive index of the skin. Other tissues may not require a lotion, especially tissues such as those of the oral cavity that may already be coated with natural moisture that will facilitate the transfer of light or other radiation.

With reference to FIGURES 1B and 1C, the functionality of the optical sensor 11 can be further understood by considering the geometry of total internal reflection in greater detail in two cases: the case in which the waveguide 5 is not in contact with the skin (FIGURE 1B showing that an air gap separates the surface 5B of the waveguide and the skin) and the case in which the waveguide is in full contact with the skin (FIGURE 1C). In the first case, a portion of the radiation from the sources that travels through the waveguide is specularly

reflected by the waveguide/air interface and another portion enters the air gap and passes therethrough to strike the skin. The radiation rays reflected and/or scattered by the skin back towards the waveguide pass through the air gap and strike the surface 5B of the waveguide. Some of the light will enter the
5 waveguide, but does so at angles (again, due to refraction at the waveguide-air interface) that in most cases result in their total internal reflection at the sidewall 5C.

When surface 5b is in air, the angle of incidence (φ) of a ray A incident
10 on the surface 5c can be equal or greater than the minimum angle at which total internal reflections occurs, as indicated by the following relation:

$$\varphi \geq \arcsin (n_m/n_w) \quad \text{Eq. (1)}$$

wherein,

15 n_m denotes the index of refraction of the medium (e.g., air) surrounding the waveguide, and.

n_w denotes the index of refraction of the material forming the waveguide.

In contrast, when the surface 5B is in contact with the skin (FIGURE 1C),
20 the back-scattered radiation rays entering the waveguide strike the sidewall at angles that allow a substantial number of those rays to leave the waveguide to reach the sensor.

In many embodiments, in order to optimize the performance of the sensor,
25 the index of refraction of the material forming the waveguide is selected to be significantly different than the index of refraction of the air. Preferably, the material forming the waveguide exhibits an index of refraction close to that of the skin, approximately $n=1.45$. In the present embodiment, the waveguide is made of fused silica having an index of refraction of approximately 1.45. In other
30 embodiments, different media may be used, for example, sapphire, which has an index of refraction of approximately 1.7.

Further, as shown schematically in FIGURE 1D, the detector 11 is preferably placed relative to the sidewall of the waveguide such that a central ray

A in a solid angle corresponding to the detector's field-of-view forms an angle θ of approximately 30 degrees relative to the sidewall 5C. Other angles are possible, and will vary depending on the physical properties of the materials involved, including the material of the waveguide, the tissue involved (skin, oral
5 tissue, and other tissues), and the material between the waveguide and the tissue (air, water, blood, etc.). Each will have a different index of refraction, and thus will result in different values for the optimal angle of the detector 11A. In some such embodiments, it may be preferable to include an additional prism on the surface (e.g., surface 5c in FIG. 1A), such as a right angle fused silica prism.)

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Referring again to FIGURE 1A, the device 1 further includes a feedback mechanism 12 in communication with the optical sensor 11, the detector 10, as well as the sources 2A and 2B. The feedback system 12 ignores the output signal from detector 10 when the optical sensor indicates no or poor optical contact
15 between the waveguide (e.g., in this embodiment, between the surface 5B of the waveguide) and the skin. During operation, however, sources 2A and 2B will be on continuously or engaged at regular intervals to check for contact. (In some embodiments, the source or sources that provide the radiation to measure a physical characteristic of the skin may also provide additional radiation for other
20 purposes, such as treatment or diagnosis. In such embodiments, the feedback system will control the source or sources to ensure that other radiation is provided at the proper time, depending on the detection of contact.)

More specifically, in this embodiment, the feedback system 12 includes a
25 processor 12A that receives the output signals of the detector 11A of the sensor. The processor compares the detector's output signal with a pre-defined threshold to determine whether an appropriate optical contact exists between the waveguide's surface 5B and the skin (a detector signal that is less than the threshold indicates no optical contact between the waveguide and the skin). If the
30 output signal of the sensor's detector is less than the threshold, the processor ignores the output of detector 10, or, alternatively, may inhibit operation of the device such that no measurement of a physical characteristic of the tissue or treatment of the tissue is provided. For example, in this embodiment, the processor 12A can send control signals to a switching unit 12B that, in turn,

ignores the output of detector 10. Sources 2A and 2B will always be engaged (either continuously or periodically) because they provide the radiation that is detected by the detector 11A to determine if the system is in contact with the tissue. (Alternatively, a separate light source could be provided that provides
5 radiation to be detected by detector 11A, and thereby allow sources 2A and 2B to be engaged only when measuring a physical characteristic of the tissue.)

As discussed in more detail below, the processor 12A also operates on the output signals received from the detector 10 to determine a skin characteristic of
10 interest. In other embodiments, the sensor 11 has its own dedicated processor that operates on the output signal of the sensor's detector 11A to determine whether or not the waveguide is in optical contact with the skin, and sends that information to the feedback system 12.

15 With continued reference to FIGURE 1A, as noted above, the processor 12A can also analyze the signals generated by the detector 10, in response to detection of the backscattered radiation from the skin illuminated by the radiation generated by the sources 2A and 2B, to determine a skin characteristic of interest, such as the concentration of melanin in the skin. The term "backscattered
20 radiation," as used herein refers to radiation that returns from the illuminated skin to the waveguide via reflection and/or scattering events.

By way of example, the device 1 can be employed in the following manner to determine the melanin concentration in a skin segment. For example,
25 the sources 2A and 2B can be sequentially activated to illuminate a skin segment that is contact with the waveguide after the optical sensor 11 detects optical contact between the waveguide's surface 5B and the skin. The sources can provide the radiation at wavelengths of 645 nm and 700 nm in different temporal intervals. A portion of the radiation illuminating the skin penetrates the skin and
30 passes through the epidermis to reach the dermis via passage through the dermis/epidermis junction (DE junction). As the skin is a turbid medium, the radiation entering the skin undergoes many scattering and/or reflection events, especially in the dermis layer. Some of the radiation is absorbed by melanin, particularly as it passes through the dermis/epidermis junction, at which the

melanin concentration is high in this example. The multiple scattering/reflection events cause some of the radiation to be coupled out of the skin back into the waveguide.

5 Due to the absorption characteristics of melanin, a relatively high level of light will be backscattered to waveguide 5, if the skin contains a relatively low amount of melanin. Conversely, a relatively low level of light will be backscattered to waveguide 5 if the skin contains a relatively high amount of melanin. As a result of the interaction of the radiation entering the skin with
10 melanin, the radiation that is backscattered into the waveguide, therefore, carries information regarding the MOD.

By way of example and without being limited to any particular theory, the intensity of the radiation backscattered from the skin into the waveguide at each
15 of the two illumination wavelengths utilized in this embodiment can be characterized by the following relation:

$$R_d^\lambda = \kappa (T_\lambda^2 R_{\text{dermis}}) \quad \text{Eq. (2)}$$

20 wherein,

R_d^λ denotes diffuse reflectance (backscattered radiation intensity) from the skin region illuminated with radiation at wavelength λ ,

κ is a proportionality constant that can depend, e.g., on the intensity of the illuminating radiation as well as geometrical factors associated with coupling
25 of the radiation into the skin,

T_λ is the transmission coefficient through the skin at the illumination wavelength λ , which depends on the melanin concentration, and

R_{dermis} denotes diffuse reflectance from the dermis.

The transmission coefficient T_λ depends on the concentration of melanin in the
30 illuminated skin region, as melanin can absorb some of the radiation. Hence, R_d^λ carries information regarding melanin concentration. In this exemplary embodiment, the radiation wavelengths are selected to be in a range of about 600 nm to about 900 nm to ensure that the interaction of the radiation with blood is

minimal. As such, the above Eq. (2) does not take into account the contributions of blood.

The apparent optical density (OD_λ) of the illuminated skin at an
5 illumination wavelength (λ) can be determined from the following relation:

$$OD_\lambda = -\log R_d^\lambda \quad \text{Eq. (3)}$$

As the above transmission coefficient T_λ is proportional to melanin optical
10 density at wavelength λ (referred to as OD_λ^{mel}), Eq. (3) can be rewritten in the following manner:

$$OD_\lambda = OD_\lambda^{mel} - \log R_{dermis} \quad \text{Eq. (4)}$$

15 The selection of the radiation wavelengths in a range of about 600 nm to about 900 nm ensures that while T_λ is wavelength dependent, R_{dermis} is substantially independent of the illumination wavelength. As such, the difference between apparent optical density (OD_λ) at two wavelengths, and more generally the slope of apparent optical density in the spectral range of about 600 nm to about 900 nm,
20 is proportional to the melanin concentration. For example, a melanin index (M) can be defined in the following manner:

$$M = 100(OD_{\lambda_1} - OD_{\lambda_2}) \quad \text{Eq. (5)}$$

25 By way of example, in many embodiments, the processor 12A employs the above mathematical relations to calculate the melanin optical density based on the detected intensity of the radiation diffusely reflected (backscattered) from the skin.

30 By way of illustration and only for the purpose of showing the efficacy of the systems and methods of the invention for measuring the skin melanin optical density, a prototype device was constructed according to the teachings of the

invention. A comparison of melanin measurements performed by that device on a number of subjects with corresponding measurements performed by a few conventional devices on the same subjects showed that the prototype device provides enhanced performance, particularly significantly better measurement repeatability. The radiation spectrum of the two LEDs utilized in the prototype device is shown in FIGURE 2. While one LED exhibits a maximum radiation intensity at a wavelength of about 645 nm, the other LED has a maximum radiation intensity at a wavelength of about 700 nm. FIGURE 3 provides raw signal generated by the detector measuring backscattered radiation for determining melanin concentration (referred to in the figure as "pigmentometer signal") in response to triggering of the LEDs in different time intervals. The raw data can be analyzed, e.g., in a manner discussed above, to arrive at the melanin index.

By way of further illustration, in another device similar to the prototype discussed above in which the wavelengths used were 660 and 910 nm respectively, FIGURE 4 shows the sensitivity of the device as a function of its tilt relative to the skin (rocking sensitivity) and FIGURE 5 shows the sensitivity of the device as a function of the thickness of air gap between the device and the skin. It should be understood that the data is presented only for illustration purposes, and is not intended to necessarily indicate the optical signal intensities that can be obtained by a device of the invention. Many other embodiments are possible, and the data provided is specific to the prototype devices that were tested, which were similar in design to the embodiment described in conjunction with device 1.

Although in the above embodiment, two sources, each of which generates radiation at a different wavelength, are employed, in some other embodiments, a single source generating radiation at two or more different wavelengths can be employed. To measure MOD, the sources preferably emit radiation in a range of about 600 nm to about 900 nm. By way of example, as shown schematically in FIGURE 6, a dermatological device 13 includes a single radiation source 14 capable of generating radiation at two or more wavelengths, e.g., a bicolour light emitting diode (bicolour LED), that is capable of generating radiation at two or

more wavelengths in a range of about 600 nm and about 900 nm. Again, the wavelengths 645 and 700 are thought to be preferable, but many other combinations of wavelengths are possible.

5 Device 13 further includes a control unit 15 having a processor 15a can actuate the bicolor LED 15 so as to generate the color of interest. For example, the control unit can cause the LED to generate the various wavelengths in different temporal intervals for illuminating a skin region of interest. More specifically, similar to the previous embodiment, the radiation generated by the
10 LED 15 is optically coupled to a waveguide 5 via passage through a polarizer 3. The waveguide 5 transmits the radiation to tissue 6, in this case human skin. A detector 10 that is optically coupled to waveguide 5 via a filter 8 and polarizer 7, receives at least a portion of the radiation that is diffusely back-reflected (backscattered) from the illuminated skin. Similar to the previous embodiment,
15 the detector 10 is coupled to the polarizer 7 having a polarization axis orthogonal to that of the polarizer 3 to suppress, and preferably eliminate, the detection of specularly reflected radiation, especially specular reflections at the surface of the illuminated skin, by the detector 10. Further, the filter 8 prevents ambient radiation noise, e.g., due to artificial ambient lighting units, from reaching the
20 detector 10.

The processor 15a receives the output signals generated by the detector 10, in response to illumination of the skin at two or more wavelengths, and analyzes those signals, e.g., in the manner discussed above, to determine a physical
25 characteristic of the skin such as the MOD. Further, similar to the previous embodiment, the device 13 includes an optical sensor 11 having a detector 11a optically coupled to a filter 9, which can determine whether the waveguide is in contact with the skin, also in a manner similar to the detector 11 as described in conjunction with FIGURE 1A.

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The embodiments of a device according to the teachings of the invention are not limited to those discussed above. For example, FIGURE 7A schematically depicts a dermatological device 16 according to another embodiment of the invention that includes a radiation source 17 whose radiation

is coupled via a prism 18 to a waveguide 19. Similar to the previous embodiments, a polarizer 3 is coupled to the source 17 and polarizes the source radiation. (Though many materials are possible, the prism in this embodiment is made of CaF_2 .) The waveguide 19 includes a reflective sidewall 19a that reflects the radiation entering the waveguide to a waveguide surface 19B that is adapted for contact with the skin. The waveguide 19 can be, for example, a block formed of a material, such as fused silica, having an index of refraction that is preferably close to that of the skin, and reflective sidewall can be formed, e.g., by coating a reflective material (such as silver) on a waveguide surface. In this embodiment, the source 17 and the prism 18 are positioned relative to the waveguide such that the radiation rays entering the waveguide are reflected by the sidewall 19a to tissue 6. The reflected radiation strikes the skin/waveguide interface at surface 19B at an angle of incidence (AOI) that, in the absence of optical contact between the surface 19B and the skin, results in total internal reflection (TIR) of those rays, thus preventing them from leaving the waveguide, as shown schematically in FIGURE 7B. For example, the angles of incidence of the rays striking the surface can be greater than the minimum angle required for causing TIR at the waveguide/air interface (See above Eq. 1) to ensure total internal reflection of those rays.

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In contrast, when the waveguide's surface 19B is in optical contact with the skin (FIGURE 7A), the rays reflected by the sidewall 19a pass through the surface 19B to enter the skin. (The waveguide/skin interface does not cause total internal reflection of those rays). The use of TIR provides an additional safety mechanism that prevents inadvertent exposure to the radiation coupled to the waveguide (e.g., exposure of a user's eye) by ensuring that radiation is emitted through the waveguide to the external environment only when the waveguide is in contact with the skin. It also increases the sensitivity of the contact sensor, because it utilizes the principle of TIR twice.

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The device 16 also includes a detector 10 that is optically coupled to waveguide 19 via a filter 8 and polarizer 7. Detector 10 detects radiation that is diffusely back-reflected (backscattered) from the skin. The device 16 also includes an optical sensor 11 having a detector 11a optically coupled to a filter 9,

which can determine whether the waveguide is in contact with the skin, also in a manner similar to the detector 11 as described in conjunction with FIGURE 1A. However, as described in conjunction with FIGURE 1A, the operation of the device is reversed. In other words, where device 1 as shown in FIGURE 1A
5 senses contact when it receives a level of light that exceeds a particular threshold, device 16 senses contact when it receives a level of light that is below a particular threshold. Like the previously described embodiments, detector 11a is optically coupled to waveguide 19 via a filter 9. Unlike the previous embodiments, the detector 11a is also optically coupled to waveguide 19 via a polarizer 4 located
10 between filter 9 and waveguide 19. Polarizer 4 has a polarization axis that is orthogonal to that associated with the source polarizer 3. Thus, device 16 suppresses the detection of specular reflections at both detectors 10 and 11a. Further, the filters 8 and 9 block ambient radiation from reaching the detectors.

15 FIGURE 8A schematically depicts a device 20 in accordance with another embodiment of the invention that also relies on reflection of light from reflective sidewalls of a waveguide to couple light into the skin and to inhibit its coupling when there is no contact between the waveguide and the skin. Rather than utilizing a single radiation source, the device 20 includes two radiation sources 22
20 and 24, each of which generates radiation at a different wavelength (e.g., in a range of 600 nm to 900 nm). The radiation sources 22 and 24 are optically coupled to a waveguide 26 via a prism 18. The waveguide 26 includes two reflective sidewalls 26a and 26b, each of which directs the light received from one of the radiation sources to a surface 26c of the waveguide such that the radiation
25 is internally reflected by that surface in absence of contact between the waveguide and the skin, and is transmitted through that surface to the skin when there is contact. The reflective sidewalls can be formed, e.g., by depositing a reflective material (e.g., silver) on the surfaces of waveguide 18. The waveguide can be formed of a material that is transmissive to the radiation generated by the sources
30 22 and 24, and, in the present embodiment, is fused silica. Similar to the previous embodiments, the radiation that is backscattered from the skin can be detected by a detector (not shown) whose output signals are analyzed by a processor (not shown) to determine a skin characteristic. Further, the sensor 11 is optically coupled to an opening 26D in the sidewall 26b, which is created by an absence of

reflective coating at the opening. The opening allows light to leak from waveguide 26 and be detected by sensor 11.

Device 20 also includes polarizers 78 and 79 and prism 80. Light sources 22 and 24 are optically coupled to waveguide 26 via the polarizers 78 and 79 and the prism 80. Polarizer 78 has a polarization axes that is orthogonal to that associated with polarizer 79, which, as discussed above, serves to eliminate surface and other reflections not associated with the parameter being measured. Additionally, sensor 11 further includes a detector 11a and a filter 9, located between detector 11a and opening 26D. The filter serves to reduce the amount of ambient radiation that reaches the detector 11a.

FIGURE 8B schematically depicts a device 100 according to another embodiment that utilizes two radiation sources 102 and 104 for illuminating the skin by coupling the radiation via a prism 106 to a waveguide 108 having two reflective sidewalls 108a and 108b, each of which is adapted for directing primarily radiation from one of those sources to the skin. The device 100 further includes two detectors 110a and 110b for detecting radiation backscattered from the skin. As in previous embodiments, the detected backscattered radiation can be analyzed by a processor (not shown) to determine a skin characteristic of interest (e.g., MOD). Similar to some of the previous embodiments, the radiation sources 102 and 104 are coupled to polarizers 112a and 112b, respectively, while the detectors 110a and 110b are coupled, respectively, to orthogonal polarizers 114a and 114b for suppressing the detection of specular reflections. Further, the detectors 110a and 110b are coupled to filters 116a and 116b, which filter out ambient radiation noise.

FIGURE 9 schematically depicts a dermatological device 27 according to another embodiment of the invention that relies on the detection of radiation transmitted through tissue 6 (in this case skin) to determine a characteristic of the tissue (in this case MOD). The exemplary device 27 includes a radiation source 14, e.g., one capable of generating radiation of at least two wavelengths in a range of about 600 nm to about 900 nm, that is optically coupled to a prism 28. The prism 28 receives the radiation from the source through a surface 28a thereof and

couples that radiation to the skin via another surface 28b, which is adapted for optical contact with the skin. The index of refraction of the material forming the prism can be selected so as to adjust the range of angles at which the radiation traveling through the prism enter the skin via refraction at the prism/skin interface. The process is similar to that described above in conjunction with device 1.

The device 27 further includes a detector 10, which is coupled to a filter 8, which filters out ambient radiation. The detector 10 is positioned at a predetermined distance from the prism to detect at least a portion of the radiation coupled by the prism 28 into the skin and transmitted through a skin portion separating the prism 28 from the detector 10. The precise angle of prism 28 and the distance between prism 28 and detector 10 can be selected to optimize a particular design, and several angles and distances could be used, some being more optimal than others. In the present embodiment, the angle at which radiation is directed to the tissue 6 is approximately 45 degrees, and the distance between prism 28 and detector 10 is approximately 1 cm. In the above device 27, the distance between the source and the detector can be adjusted to tune the device for measuring the concentration of a given chromophore (pigment) of interest at different skin depths, for example, by selecting wavelengths that are better absorbed by deeper tissues or over longer distances, by adjusting the distance between the prism 28 and the detector 10, and/or by utilizing additional wavelengths and/or detectors to differentiate the relative amounts of the chromophore at different positions or depths in the tissue 6.

The light entering the skin is transmitted diffusely (via multiple scattering and/or reflections events) to the detector. The transmitted light can also carry information regarding the concentration of a chromophore of interest, as a result of its interaction with that chromophore (e.g., via absorption of some of the light by the chromophore). A processor 29 in electrical communication with the detector 10 and light source 14 analyzes the detector's output signals generated in response to illumination of the skin at two or more radiation wavelengths (e.g., two wavelengths in a range of about 600 nm to about 900 nm) to determine a characteristic of the skin, such as melanin optical density.

The device 27 provides a high sensitivity in measuring the concentration of a pigment of interest, as it relies on diffuse transmission of photons over a long distance through the skin. This allows the device to be employed in a variety of applications. By way of example, as shown schematically in FIGURE 10, the device 27 can be employed to detect an iris 30 within the eye. For example, as the device 27 is scanned over the skin, it can detect significant absorption of the radiation transmitted through the illuminated skin (especially at wavelengths in a range of about 600 to about 800 nm) by the iris 30, thereby detecting its presence. Such detection of the iris can be useful, for example, in devices that must avoid damaging an eye when providing laser or other radiation treatment to the skin. The device 27 can be incorporated in such treatment devices to provide a signal when the treatment device is over the eye, and preferably inhibit activation of (or deactivate) the treatment laser source based on such eye detection signal.

15

In other embodiments, the dermatological devices of the invention can employ optical fibers for coupling radiation from a source into the skin and/or decoupling radiation backscattered by or transmitted through an illuminated skin segment. By way of example, FIGURE 11A schematically depicts a dermatological device 32 according to such an embodiment of the invention that includes a source 12 optically coupled to a plurality of optical fibers 33, each of which receives the radiation generated by the source at one end thereof and, during operation, can be optically coupled at another end to a tissue 6 (in this case, skin). In many embodiments, the source 12 is capable of generating radiation at two or more wavelengths, e.g., two or more wavelengths in a range of about 600 nm to about 900 nm. The device 32 further includes another set of optical fibers 34, each of which is optically coupled at one end thereof to the skin at a location separated by a selected distance from the location at which the radiation enters the skin via the fibers 33a. In this manner, the optical fibers 34 collect at least a portion of the radiation that is diffusely transmitted (radiation transmitted via multiple scattering and/or reflection events) through a skin portion disposed between the ends 33a of the fibers 33 and the ends 34a of the fibers 34, and is coupled into the fiber 34, e.g., via scattering/reflection events. Each of the optical fibers 34 is optically coupled at another end, via the a filter 8 that filters

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out ambient radiation noise, to a detector 10 that receives the radiation collected by the optical fibers 34.

5 A processor 36 processes the output signals of the detector 10 to determine a characteristic of the illuminated skin segment. For example, in cases where a measurement of the melanin optical density of the skin is desired, the source 14 can be selected to provide at least two radiation wavelengths in a range of about 600 nm to about 900 nm. The source can be activated to illuminate the skin 6 via the fibers 33 at these two wavelengths in different temporal intervals. And the
10 output detection signals generated by the detector 10 corresponding to the two illumination wavelengths can be analyzed by the processor 36 to determine the melanin concentration by utilizing, e.g., the mathematical equations discussed above.

15 In another embodiment schematically shown in FIGURE 11B, a dermatological device 37 in accord with the teachings of the invention includes a plurality of optical fibers 38 for transmitting the radiation generated by a source 14 to tissue 6. Waveguides 39 guide the radiation from tissue 6 to a detector 10. Waveguides 39 have a substantially cylindrical hollow structure, as shown in
20 FIGURE 11C. Waveguides 39 collect at least a portion of the radiation transmitted through the skin from the illumination site to the waveguide. A detector 10 is optically coupled to the waveguide, via a filter 8, to receive the radiation collected by the waveguide. Similar to the previous embodiment, a processor 36 operates on the output signals generated by detector to determine a
25 desired characteristic of the skin.

As shown in FIGURE 11D, in some embodiments, the cylindrical waveguide is formed by disposing a plurality of optical fibers 39a within an annular housing 39b, e.g., a flexible enclosure. In some alternative embodiments,
30 the waveguide can be an annulus formed of a suitable material, such as fused silica. By way of further illustration, FIGURE 11E schematically depicts a top view of an area 40 under observation (the sensing area) by the device 37. The perimeter of the sensing area is defined by a proximal end of the cylindrical waveguide 39 shown in FIGURES 11C and 11D. The radiation energy is coupled

into the area 40 via a proximal end of optical fibers 38 (the area 38b illustrates the top view of the skin area illuminated by the fibers 38). In this embodiment, the waveguide can be selected such that sensing area is large so as to reduce measurement sensitivity to local irregularities. However, other embodiments can be sized to provide relatively larger sensing areas or relatively smaller sensing areas. Additionally, alternate embodiments can include other configurations such as an internal waveguide located inside waveguide 39 that replaces fibers 38. Similarly, light can be provided to the sensing area through a hollow space within the waveguide 39 without using fibers 38 or another waveguide.

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By way of another example, FIGURE 12 schematically depicts a dermatological device 42 that includes an optical fiber 43. Optical fiber 43 comprises a core 43a surrounded by a cladding 43b. Optical fiber 43 is optically coupled at a proximal end thereof to a radiation source 44 to receive radiation from the source after its passage through a beam splitter 45, and is coupled at its distal end to a skin region 6 to transmit the received radiation to the skin. The radiation that is backscattered into the fiber from the illuminated skin region travels back through the fiber along the same path and exits from the proximal end towards the beam splitter 45, which in turn directs the backscattered radiation to a detector 46, which is coupled to a filter 47. A processor 48 determines one or more characteristics of the skin based on the output signals generated by the detector. By way of example, in some embodiments, the radiation source 44 provides two or more radiation wavelengths, e.g., two or more wavelengths in a range of about 600 nm to about 900 nm, and the processor analyzes the output signals of the detector 46 corresponding to backscattered radiation at these wavelengths to determine a skin characteristic (e.g., melanin concentration), e.g., in a manner discussed above.

In this embodiment, the device 42 further includes an optical sensor 49, having a detector 49a coupled to a filter 49b, that is optically coupled to the fiber 43 at a fiber section A from which the cladding is removed. The removal of the cladding allows a portion of the backscattered radiation to leak from the core into the sensor's detector. The detection signal generated by the sensor's detector can then be utilized to determine whether the fiber's distal end is in contact with the

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skin. For example, the detection of radiation intensity below a selected threshold by the sensor can indicate lack of contact between the fiber's distal end and the skin while the detection of radiation above that threshold can indicate contact.

5 FIGURE 13 schematically depicts a dermatological device 50 in accordance with another embodiment of the invention that also employs an optical fiber 51 for coupling radiation into the skin and collecting radiation backscattered from the illuminated skin. More specifically, optical fiber 51 has a split end 52 that provides an input port 52a optically coupled to a radiation source
10 53 for receiving radiation from the source, and an output port 52b for coupling radiation backscattered into the fiber to a detector 54, via a filter 55. Similar to some of the previous embodiments, the source can provide two or more wavelengths of interest and the output of the detector 54 corresponding to the backscattered radiation at those wavelengths can be analyzed by a processor (not
15 shown) to determine a skin characteristic (e.g., the skin's melanin index).

Although the majority of the embodiments described herein are used for the measurement of MOD of skin by applying radiation at the surface of the skin, other embodiments are possible, both for measuring other characteristics and
20 other tissues. For example, given the potentially small size of the embodiments described in conjunction with FIGURES 11A-13, alternate embodiments of devices employing these concepts could be use to measure physical properties of internal tissues, for example, via an endoscope and/or incision.

25 A diagnostic dermatological device according to the teachings of the invention, such as those discussed above, can be coupled to a dermatological treatment device to provide information regarding one or more characteristics of the skin to be treated. For example, as shown schematically in FIGURE 14, a dermatological device 56 can include a treatment module 57 and a diagnostic
30 module 58 that is in communication with the treatment module. By way of example, the treatment module can include a radiation source 59 that provides treatment radiation. The treatment radiation can be coupled via one or more optics (not shown) through a radiation transmissive window 60 (such as a sapphire window) to the skin. Alternatively, the treatment module can receive the

treatment radiation from an external source, e.g., via an optical fiber. By way of example, U.S. Patent Appl. No. 10/154,756 entitled "*Cooling System for a Photocosmetic Device*," which is herein incorporated by reference, provides teachings regarding dermatological treatment devices that can be employed in constructing the treatment module 57. In this embodiment, the treatment module includes a feedback mechanism 62 that is in communication with the treatment source 59 and the diagnostic module 58. The feedback mechanism 62 can receive signals from the diagnostic module indicative of one or more skin characteristics, e.g., the melanin optical density.

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In this exemplary embodiment, the feedback mechanism 62 applies control signals to the radiation source in response to the information regarding the skin characteristic received from the diagnostic module to adjust one or more parameters of the treatment radiation generated by the source, e.g., the power of treatment radiation, the wavelength of the treatment radiation, pulse width and/or pulse repetition rate when pulsed radiation is used, or any other parameter of interest. In some cases, the diagnostic module can be utilized to allow activation of the treatment source only for treating certain skin types. For example, the treatment radiation source can be activated to treat only those persons whose skin pigment levels (e.g., MOD) would result in the diagnostic wavelength signal, the ratio of the diagnostic signals at different wavelengths, as well as the background signals falling within predefined ranges (e.g., above or below certain thresholds.) By way of example, such parameters can be set such that most materials other the skin would provide diagnostic signals outside a range that would be acceptable for activating the treatment source. For example, when the skin characteristic corresponds to the MOD, the feedback module can control the treatment source to adjust its output power, e.g., to reduce the power when the measured melanin optical density is high and to increase it when that optical density is low. Further, in some cases in which the skin melanin concentration is above a predefined threshold, the feedback mechanism can inhibit activation of the treatment source. This can be utilized, e.g., as a safety measure to ensure that the treatment radiation is applied only when appropriate (e.g., only to the skin having pigment levels within a predefined range).

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In some embodiments, such adjustment of one or more parameters of the treatment radiation in response to the information provided by the diagnostic module can be accomplished in real-time. For example, as the device 56 is moved over the skin, the treatment module 57 lags behind the diagnostic module 58 such that the diagnostic module determines a desired characteristic of a skin segment to be treated prior to application of the treatment radiation to that segment by the treatment module. In this manner, the treatment module can utilize the information provided by the diagnostic module to adjust the treatment parameters (e.g., the power level of the treatment radiation) in real-time. For example, different portions of a skin patch under treatment can exhibit different pigment levels (e.g., different melanin concentrations). In such a case, the treatment module can adjust the power level of the treatment radiation as the treatment radiation is applied to those skin portions.

In embodiments in which the treatment source is external to the treatment module, the adjustment of one or more parameters of the treatment radiation in response to information provided by the diagnostic module can be achieved, e.g., by applying control signals to the source and/or to one or more elements disposed in the treatment module and in optical coupling with the source. For example, a shutter disposed within the treatment module can be controlled to allow or inhibit application of the treatment radiation to the skin based on one or more skin characteristics determined by the diagnostic module. Further, one or more neutral density filters can be utilized to modulate the power level of the treatment radiation.

With continued reference to FIGURE 14, the exemplary device 56 further includes a speed sensor 64 that measures the device's scanning speed as it scans the skin. The speed sensor can be configured to allow a directional scan (uni-directional in this case, although other embodiments are possible, including bi-directional and multi-directional) such that the diagnostic module 58 would lead the treatment module. Examples of speed sensors suitable for use in the device 56 can be found in U.S. Patent Application No. 11/098,015, filed April 1, 2005 entitled "*Methods and products for producing lattices of EMR-treated islets in tissues, and uses therefore,*" which is herein incorporated by

reference. In some embodiments, the feedback mechanism can be incorporated within the speed sensor.

5 In some embodiments, the treatment and the diagnostic modules, and in some cases the speed sensor as well, can be integrated within a single enclosure so as to provide a compact device. Further, in many such embodiments, the diagnostic and the treatment sources can share a common optical path so that a tissue region can be treated in real-time as its one or more characteristics (such as melanin optical density) are measured. Such a device can be particularly useful
10 when the treatment is applied in a stamping mode.

By way of example, FIGURE 15 schematically depicts a dermatological device 65 having an enclosure 66 in which a treatment radiation source 67 for generating treatment radiation and a radiation source 68, e.g., a source generating
15 two or more wavelengths are disposed. The radiation from the treatment source is coupled via a lens 69, after passage through a beam splitter 70, into a waveguide 71, e.g., a sapphire block. The radiation from the source 68 passes through a beam splitter 72 to be reflected by the beam splitter 70 into the waveguide. The waveguide 71 guides both the treatment and the radiation into a skin region in
20 contact therewith. A portion of the radiation that is backscattered from the illuminated skin region is reflected by the beam splitters 72 and 70 into a detector 73 via a filter 74. Detector 73 generates output signals that can be analyzed by a processor 75, e.g., in a manner discussed in connection with the previous embodiments, to determine a characteristic of the tissue 6 (e.g., the melanin
25 concentration of skin). The device 65 can further include an optical sensor 76, such as those discussed above, that is optically coupled to a sidewall of the waveguide 71 for determining contact between the waveguide and the skin. The processor can operate on the output signals generated by the sensor to control the treatment radiation source (e.g., inhibit its activation and/or deactivate it when
30 there is no contact between the waveguide and the skin). In addition, the processor can further adjust one or more parameters of the treatment radiation (e.g., power level, pulse width, or repetition rate) in response to the output signals of the optical sensor 76. Similar to certain embodiments discussed above, a plurality of polarizers and filters can be employed to suppress detection of

radiation specularly reflected at various interfaces and/or ambient radiation.

Further, in some embodiments, the device 65 can include a speed sensor 77 that can measure the speed of the device 65 as it is scanned over the skin, and in some cases apply control signals to the treatment source (e.g., modulate the source's power in response to the scan speed).

5 In other embodiments, more than two wavelengths can be used to detect a physical property of the skin. For example, by using three wavelengths, the apparent age of the skin can be determined. The backscattered radiation from a skin region can be measured using three or more wavelengths. Although many wavelengths are possible, the wavelengths chosen are preferably in a range of about 600 nm to about 900 nm, such as 645, 700 and 900 nm. As in the case of measuring MOD, selection of wavelengths in this range takes advantage of the absorption characteristics of skin in that wavelength range. The age of the skin can correspond to its chronological age or its apparent age. For example, in some cases, the skin of a young individual (e.g., a person in her twenties) may nonetheless exhibit a much older apparent age, e.g., due to excessive sun exposure and/or smoking. The devices discussed above can be employed to practice this aspect of the invention, e.g., by selecting an appropriate radiation source (or sources) that provide the requisite radiation wavelengths. Reflectance values at these three wavelengths can be analyzed to determine MOD and skin diffusion properties, and the skin age can be correlated to the skin diffusion properties.

Similarly, by using three or more wavelengths, the error in measurement can be reduced. For example, two wavelengths can be selected that are close in value (e.g., approximately 10 nm apart) while the third wavelength is further spaced, e.g., 640, 650 and 700 nm. The use of the additional wavelength will help reduce errors due to inconsistencies in measurements caused by other physical characteristics of the tissue.

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In some embodiments, the wavelength of the radiation generated by a radiation source utilized for providing radiation can depend to some degree on the temperature of that source. In such embodiments, wavelength versus temperature data for the radiation source(s) can be stored, e.g., on a memory module, to be

utilized by the processor to calibrate the radiation wavelength (to calculate the actual wavelength from the nominal wavelength).

Although the above embodiments generally described utilizing
5 wavelengths in a range of about 600 nm to about 900 to measure, e.g., the MOD
of skin, the various embodiments discussed above can be generally employed
with radiation source generating radiation with wavelengths in other ranges
including a range of about 300 nm to about 1200 nm to measure the concentration
of other chromophores (such as hemoglobin). For example, two forms of
10 hemoglobin have primary absorption bands in a spectral range of 405 nm to 430
nm (the Soret band) and secondary bands in a range of 540 nm to 580 nm. In
some embodiments, the concentration of the hemoglobin can be measured by
detecting the backscattered radiation at two or more wavelengths in those bands.
Even broader or different wavelength ranges can be used for other purposes or to
15 use other types of radiation sources.

Those having ordinary skill in the art will appreciate that various
modifications can be made to the above embodiments without departing from the
scope of the invention.
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What is claimed is:

CLAIMS:

1. A dermatological device for determining a physical characteristic of a portion of tissue, comprising:
- 5 a radiation source assembly configured to generate radiation having at least a first wavelength;
- a waveguide coupled to said source assembly for directing the
- 10 radiation from the source to said portion of said tissue, and having a surface configured to irradiate said portion with said radiation;
- a detector coupled to said waveguide and configured to detect radiation from said source, said detector generating signals indicative of the level of
- 15 radiation detected; and
- a processor in communication with said detector to process said signals and calculate a physical characteristic of the skin region;
- 20 wherein said detector is configured to detect said radiation from said source after said portion of said tissue has been irradiated with said radiation from said source.
2. The device of claim 1, wherein said radiation source assembly includes
- 25 two or more radiation sources.
3. The device of claim 2, wherein a first radiation source produces radiation having said first wavelength and wherein a second radiation source produces radiation having a second wavelength.
- 30 4. The device of claim 1, wherein said radiation source assembly includes a single radiation source.

5. The device of claim 4, wherein said first radiation source produces radiation having said first wavelength and further produces radiation having a second wavelength.
- 5 6. The device of claim 1, wherein said radiation source assembly includes at least one of a light emitting diode (LED), a bi-color LED, a tunable radiation source, and a laser radiation source.
7. The device of claim 1, wherein said radiation source assembly is
10 configured to generate radiation having a second wavelength.
8. The device of claim 7 wherein said first and second wavelengths are selected from a range of about 350 nm to about 1200 nm.
- 15 9. The device of claim 7 wherein said first and second wavelengths are selected from a range of about 600 nm to about 900 nm.
10. The device of claim 1 wherein said first wavelength is selected from a range of about 350 nm to about 1200 nm.
20
11. The device of claim 1 wherein said first wavelength is selected from a range of about 600 nm to about 900 nm.
12. The device of claim 1, further comprising a contact sensor indicating
25 whether said surface of the optical waveguide is in contact with the skin.
13. The device of claim 12, wherein said contact sensor is configured to detect a level of said radiation of said first wavelength.
- 30 14. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is not in contact with said tissue when said contact sensor detects that said level is below a threshold.

15. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is in contact with said tissue when said contact sensor detects that said level is above a threshold.

5

16. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is not in contact with said tissue when said contact sensor detects that said level is above a threshold.

10

17. The device of claim 13, wherein said contact sensor is configured to send a signal to said processor indicating that said surface of said waveguide is in contact with said tissue when said contact sensor detects that said level is below a threshold.

15

18. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to totally internally reflect said radiation along said boundary when said surface is not in contact with said tissue.

20

19. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to not totally internally reflect said radiation along said boundary when said surface is in contact with said tissue.

25

20. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to totally internally reflect said radiation along said boundary when said surface is in contact with said tissue.

30

21. The device of claim 12, wherein said contact sensor is optically coupled to said waveguide along a boundary and wherein said waveguide is configured to not totally internally reflect said radiation along said boundary when said surface is not in contact with said tissue.

22. The device of claim 12, wherein said radiation source assembly is configured to generate radiation having a second wavelength, and said contact sensor is configured to detect a level of said radiation of said first wavelength
5 and of said second wavelength.

23. The device of claim 12, further comprising:

a first polarizer configured to filter radiation of a first polarity from
10 said radiation source assembly; and

a second polarizer configured to filter radiation of a second polarity entering said contact sensor.

15 24. The device of claim 12, further comprising a filter disposed between the contact sensor and the waveguide.

25. The device of claim 1, wherein said radiation source assembly is configured to generate radiation having three or more wavelengths.

20

26. The device of claim 1, wherein said skin characteristic is selected from the group consisting of melanin index, collagen content, diffusion, and erythema measurement.

25 27. The device of claim 1 wherein said waveguide is formed of a material having an index of refraction in a range of about 1.4 to about 2.5.

28. The device of claim 1, further comprising:

30 a first polarizer configured to filter radiation of a first polarity from said radiation source assembly; and

a second polarizer configured to filter radiation of a second polarity entering said detector.

29. The device of claim 1, further comprising a filter disposed between said waveguide and said detector.

5

30. The device of claim 1, further comprising a controller coupled to said radiation source assembly, said controller configured to activate said radiation source assembly to produce radiation of different wavelengths at different times.

10

31. The device of claim 1, wherein said waveguide is an optical fiber.

32. The device of claim 1, further comprising at least one additional waveguide coupled to said source assembly.

15

33. The device of claim 32, wherein said at least one additional waveguide is an optical fiber.

20

34. A dermatological device for determining a physical characteristic of a portion of tissue, comprising

a radiation source assembly configured to generate radiation having first and second wavelengths;

25

a waveguide coupled to said source assembly for directing the radiation from the source to said portion of said tissue, and having a surface configured to irradiate said portion with said radiation;

30

a detector coupled to said waveguide and configured to detect radiation from said source, said detector generating signals indicative of the level of radiation detected;

a processor in communication with said detector to process said signals and calculate a physical characteristic of the skin region; and

a contact sensor optically coupled to said waveguide along a boundary and configured to detect a level of said radiation;

5 wherein said detector is configured to detect said radiation from said source after said portion of said tissue has been irradiated with said radiation from said source.

35. The device of claim 34, wherein said first and second wavelengths are
10 in a range of about 300 nm to about 1200 nm.

36. The device of claim 34, wherein said first and second wavelengths are in a range of about 600 nm to about 900 nm.

15 37. The device of claim 34, wherein said first and second wavelengths are in a range of about 630 nm to about 730 nm.

38. The device of claim 34, wherein said first wavelength is approximately 645 nm.
20

39. The device of claim 34, wherein said first wavelength is approximately 700 nm.

40. The device of claim 34, wherein said first wavelength is approximately
25 645 nm and said second wavelength is approximately 700 nm.

41. The device of claim 34, wherein said waveguide surface adapted for contact with the tissue inhibits transmission of radiation in absence of skin contact by total internal reflection of radiation reflected by the sidewall
30 thereof.

42. The device of claim 34, further comprising a feedback mechanism in communication with said sensor and said source, wherein said feedback mechanism is capable of inhibiting activation of the source when the sensor

indicates lack of optical contact between the waveguide and the source, and capable of activating the source when the sensor indicates optical contact.

43. The device of claim 34, further comprising a processor in
5 communication with the detector, said processor determining a skin characteristic based on said detector output.

44. The device of claim 34, wherein said waveguide is an optical fiber.

10 45. The device of claim 34, further comprising at least one additional waveguide.

46. A dermatological device, comprising
15 at least one radiation source,

a waveguide optically coupled to the radiation source to transmit radiation from the source to the skin, said waveguide having two opposed surfaces and a sidewall extending between said surfaces,

20 a detector coupled to the waveguide to detect at least a portion of radiation backscattered from a skin region illuminated by the source radiation, and

25 an optical contact sensor optically coupled to said sidewall, said sensor determining whether said waveguide is in contact with the skin based on detection of backscattered radiation leaking through said sidewall.

47. A dermatological device, comprising:
30 a radiation source assembly;

a first waveguide having a proximal end adapted to receive radiation from the radiation source assembly and a distal end adapted to transmit radiation to a tissue;

5 a second waveguide having a distal end adapted to receive backscattered radiation from said first waveguide and a proximal end adapted to transmit said backscattered radiation;

a detector optically coupled to said second waveguide and configured
10 to measure a physical characteristic of said tissue; and

a processor electrically coupled to the detector and configured to receive a signal from said detector corresponding to said backscattered radiation;

15

wherein said processor is configured to determine a physical characteristic of said tissue based on the backscattered radiation that is detected.

20 48. The device of claim 47, wherein the device further comprises a means for coupling said backscattered radiation exiting from said proximal end to the detector.

49. The device of claim 48, wherein said means comprises a beamsplitter.

25

50. The device of claim 47, wherein the radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 350 nm to about 1200 nm.

30 51. The device of claim 47, wherein the radiation source assembly is capable of generating radiation at two or more wavelengths in a range of about 600 nm to about 900 nm.

52. The device of claim 47, wherein the first waveguide is an optical fiber.

53. The device of claim 47, wherein the second waveguide is an optical fiber.
- 5 54. The device of claim 47, further comprising additional waveguides
55. The device of claim 54, wherein said additional waveguides are optical fibers.
- 10 56. A dermatological device, comprising
- at least one source of radiation,
- an optical fiber receiving radiation from said source at a proximal end
- 15 and applying the radiation to a skin region at a distal end,
- another optical fiber coupled at a distal end to skin at another region separated from the illuminated region by a skin segment so as to receive at least a portion of the applied radiation after transmission through that segment,
- 20 a detector optically coupled to a proximal end of said another optical fiber to detect at least a portion of said transmitted radiation received by that fiber, said detector generating a signal indicative of an intensity of said received radiation, and
- 25 a processor operating on said detector signal to determining a skin characteristic.
- 30 57. A method of determining a characteristic of tissue comprising:
- applying radiation of first and second wavelengths from a waveguide to said tissue;

detecting at least a portion of radiation of said first and second wavelengths backscattered from said tissue

generating at least one signal indicative of an intensity of the backscattered radiation, and

processing said at least one signal to calculate a characteristic of the skin region.

58. The method of claim 57, wherein the step of applying radiation further comprises applying radiation at a plurality of wavelengths selected from a range of about 350 nm to about 1200 nm. to the skin.

59. The method of claim 57, wherein the step of applying radiation further comprises applying radiation at a plurality of wavelengths selected from a range of about 600 nm to about 900 nm.

60. The method of claim 57, further comprising detecting optical contact between the waveguide and the skin region.

61. The method of claim 57, further comprising sensing contact of said waveguide with said tissue by detecting a level of said backscattered radiation.

62. The method of claim 57, further comprising reducing ambient radiation to prevent its detection by the detector.

63. The method of claim 64, further comprising:
reducing radiation having a first polarity prior to detection; and
detecting radiation having a second polarity.

FIG. 1A

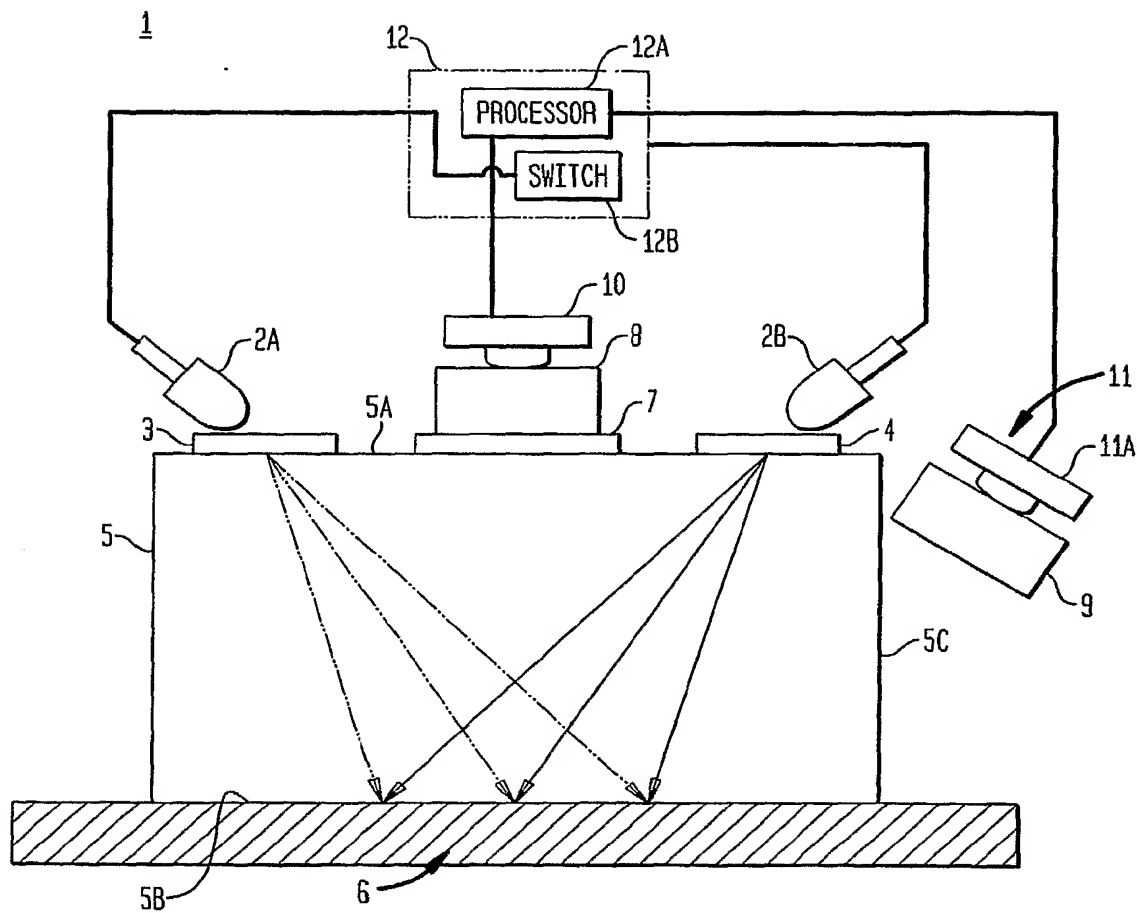


FIG. 1B

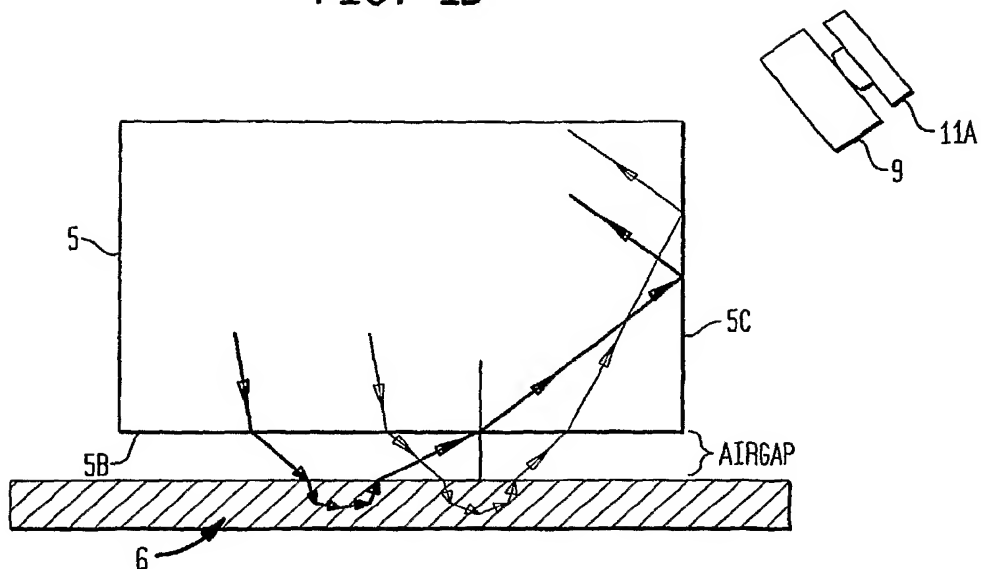
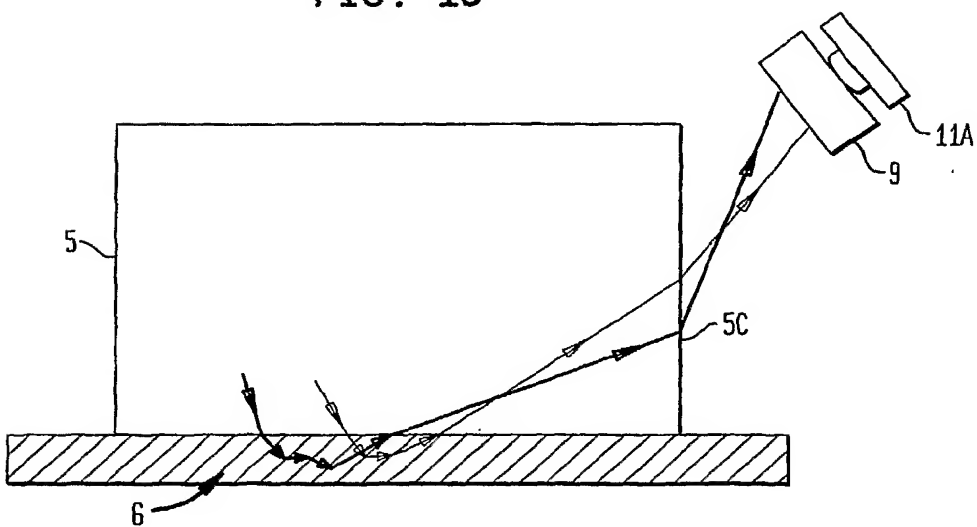


FIG. 1C



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FIG. 1D

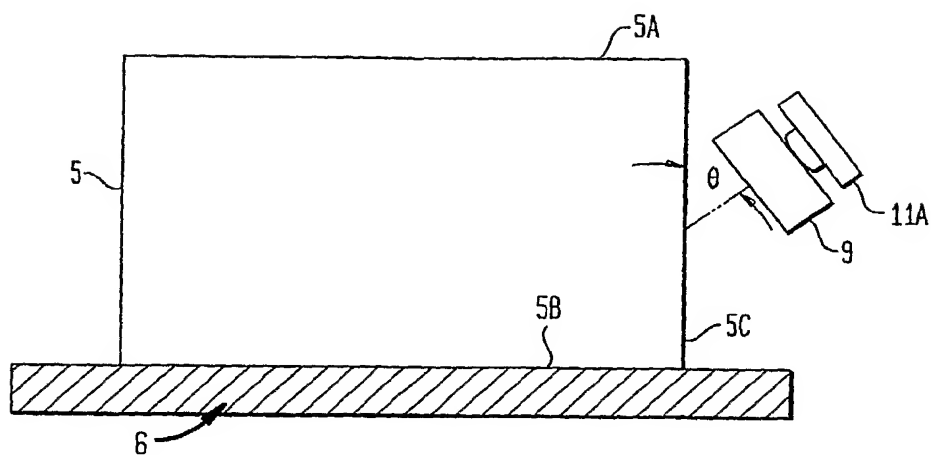
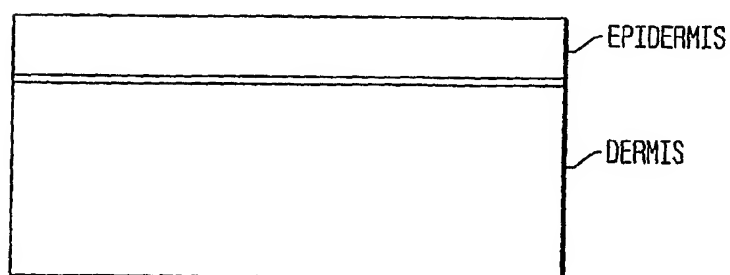


FIG. 1E



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FIG. 1F

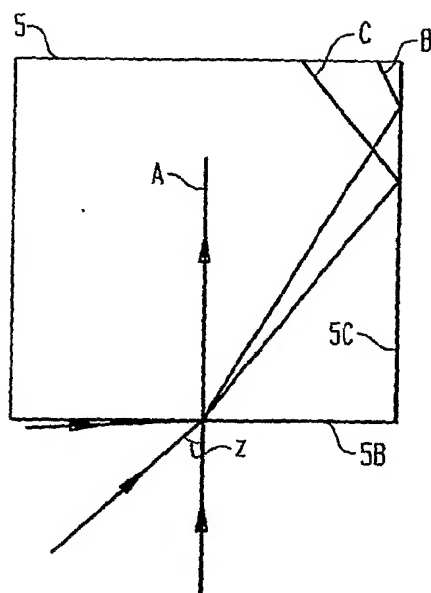


FIG. 1G

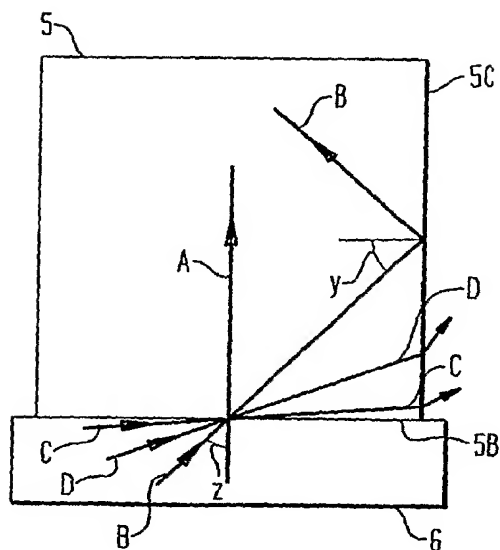
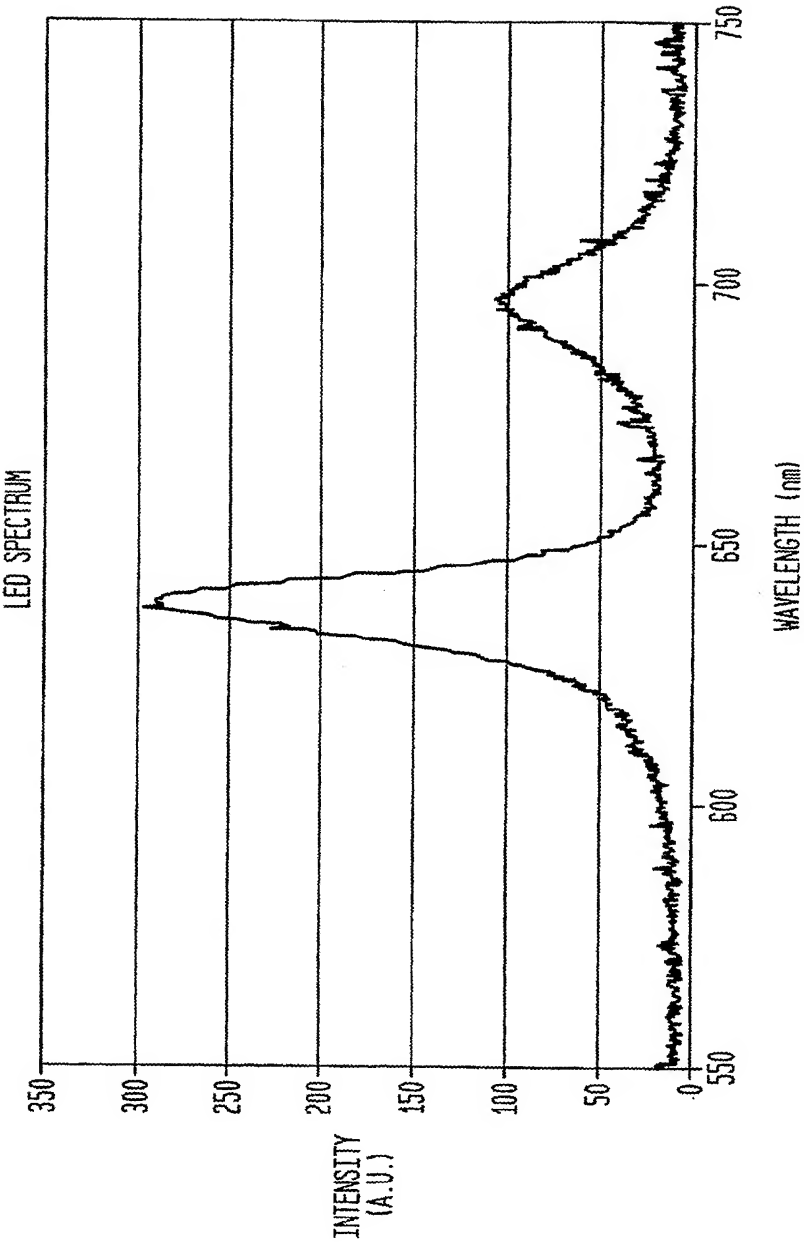
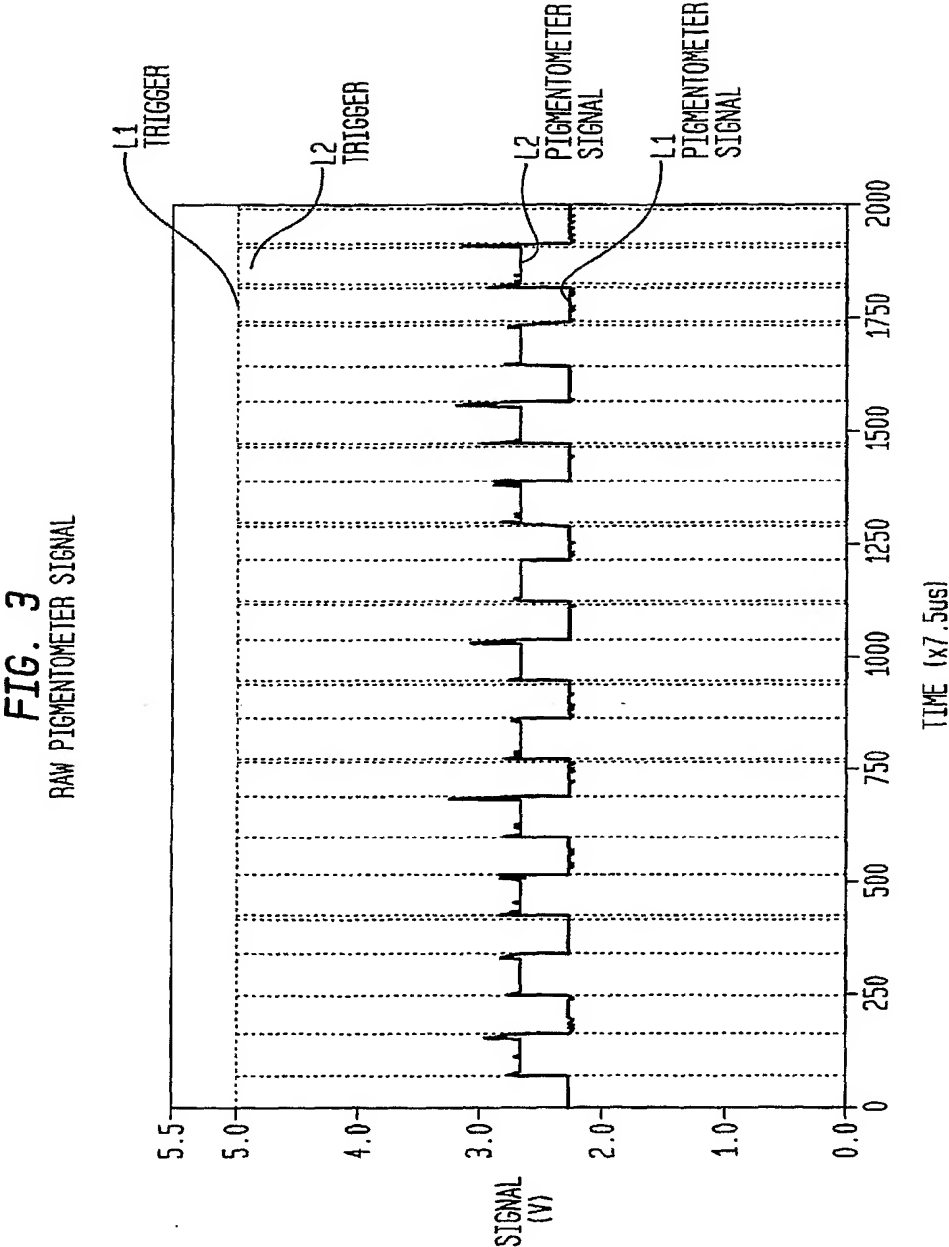


FIG. 2
LED 1 AND 2





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FIG. 4
ROCKING SENSITIVITY (660 vs 910 nm)

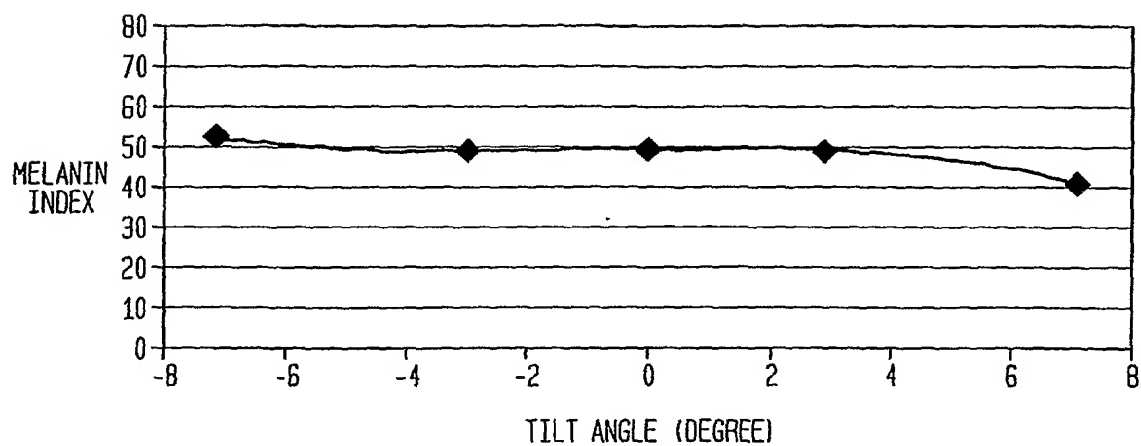
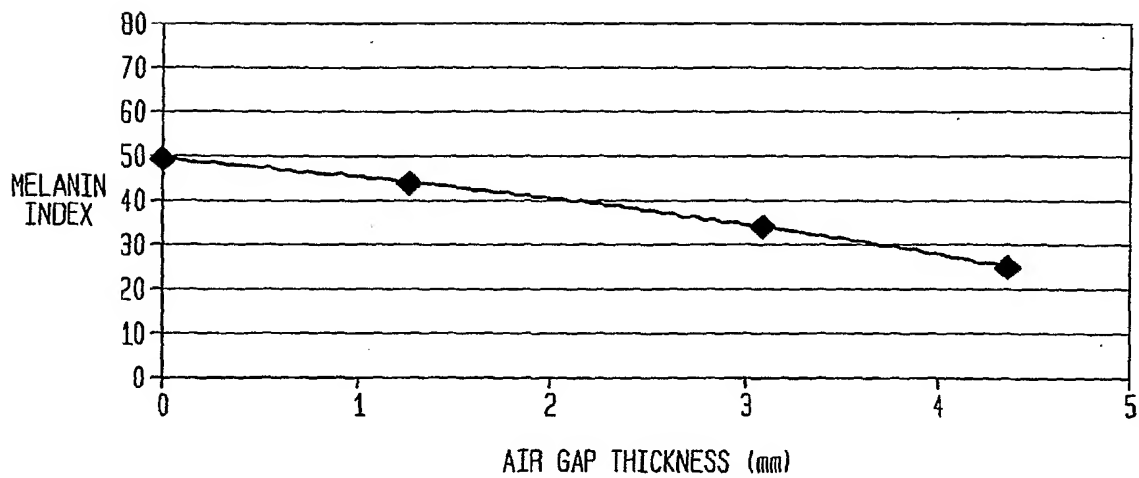
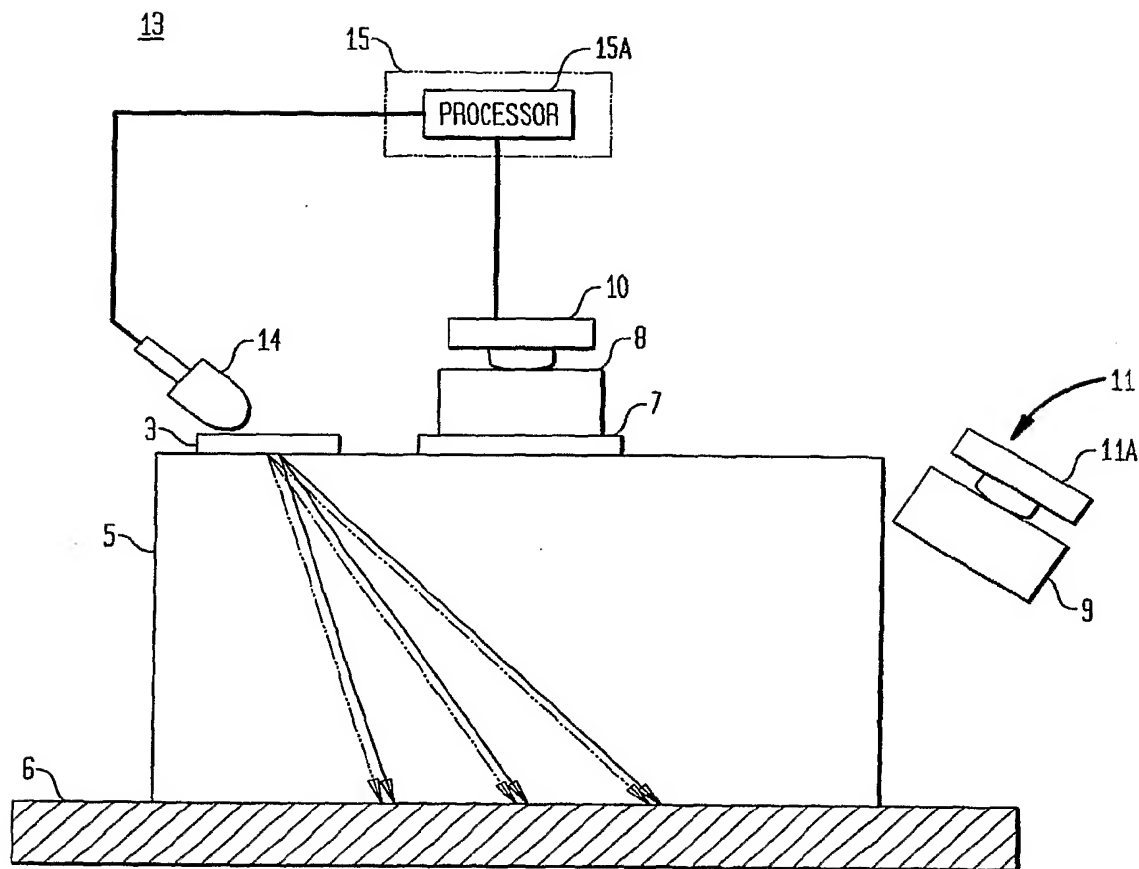


FIG. 5
AIR GAP SENSITIVITY (660 vs 910 nm)



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FIG. 6



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FIG. 7A

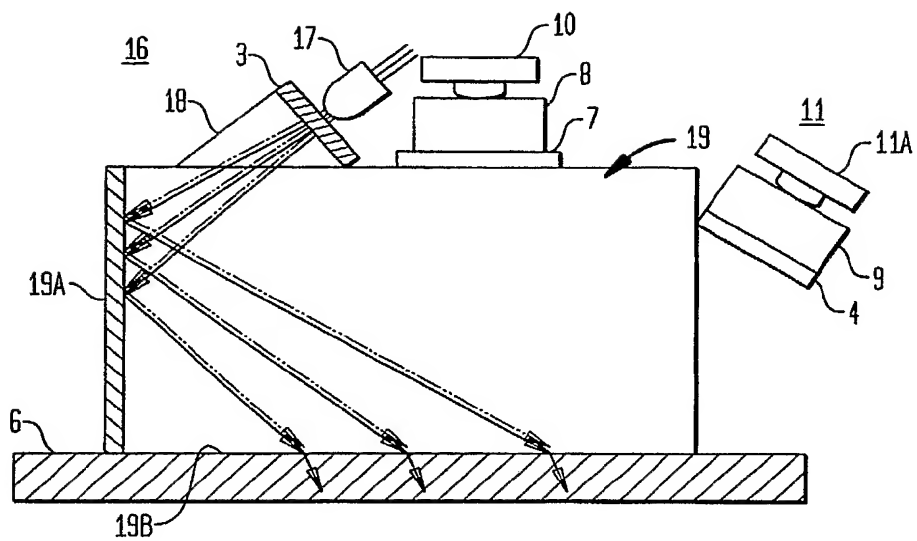
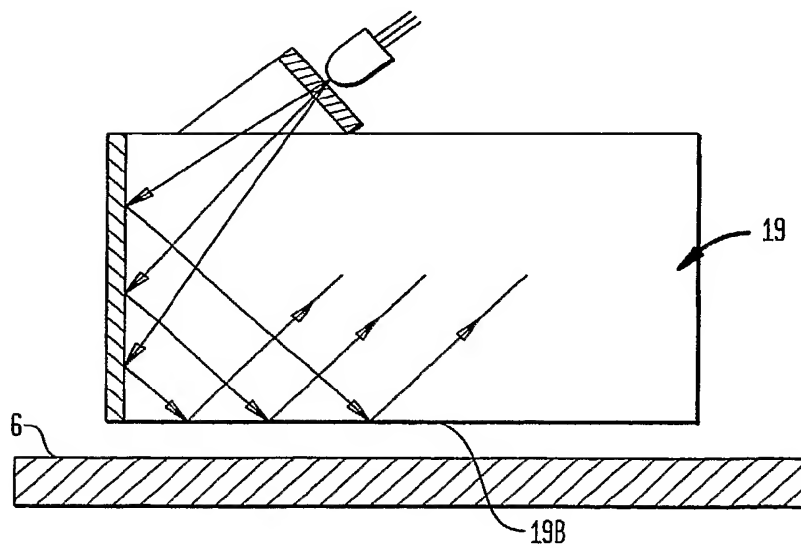
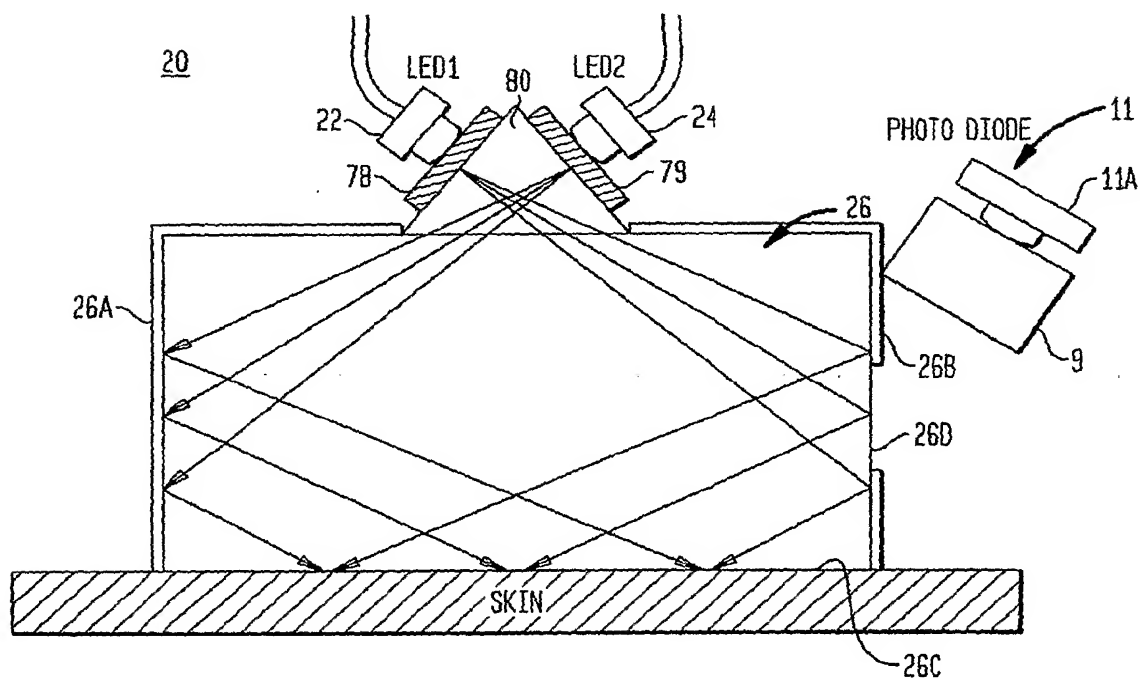


FIG. 7B



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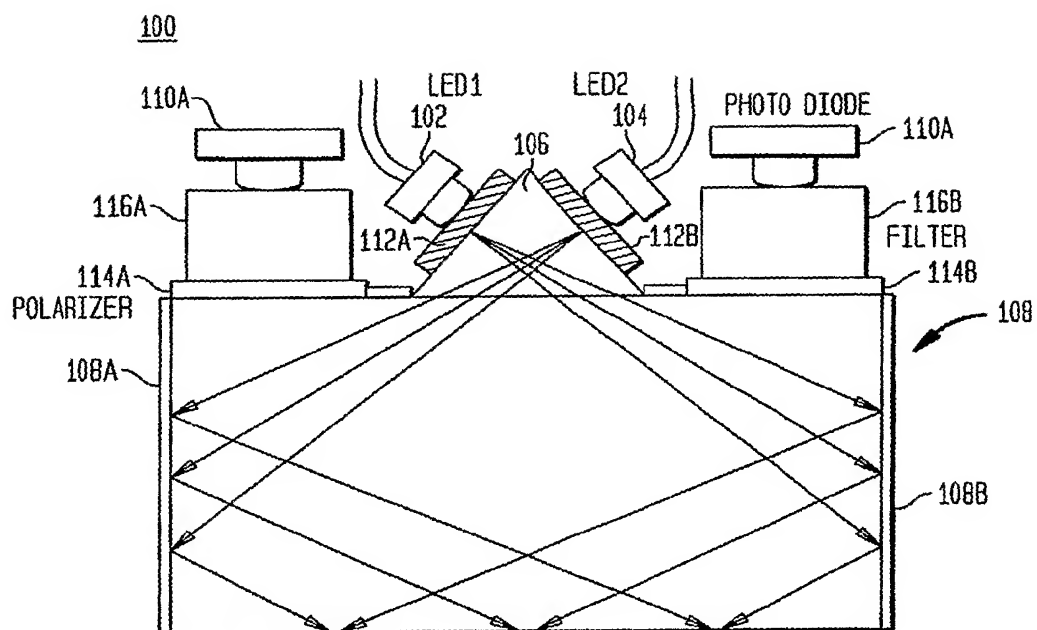
FIG. 8A
TIR COUPLING AND TIR DECOUPLING DESIGN



SUBSTITUTE SHEET (RULE 26)

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FIG. 8B



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FIG. 9

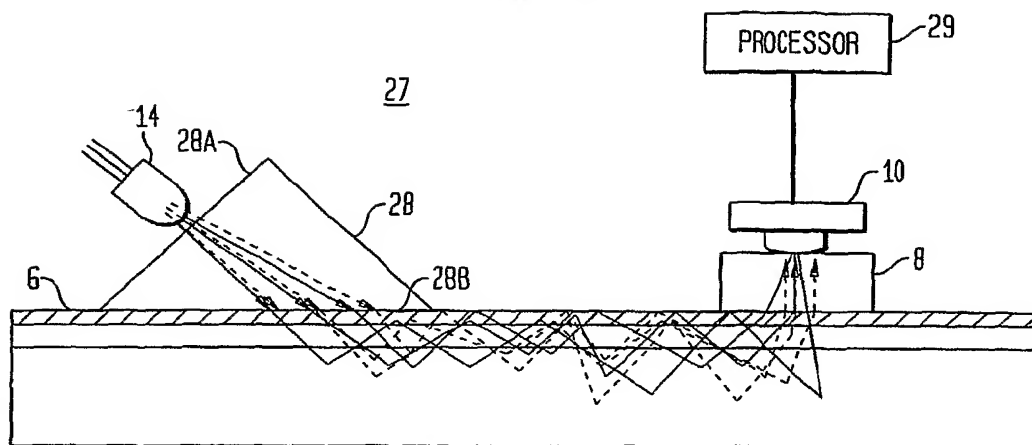
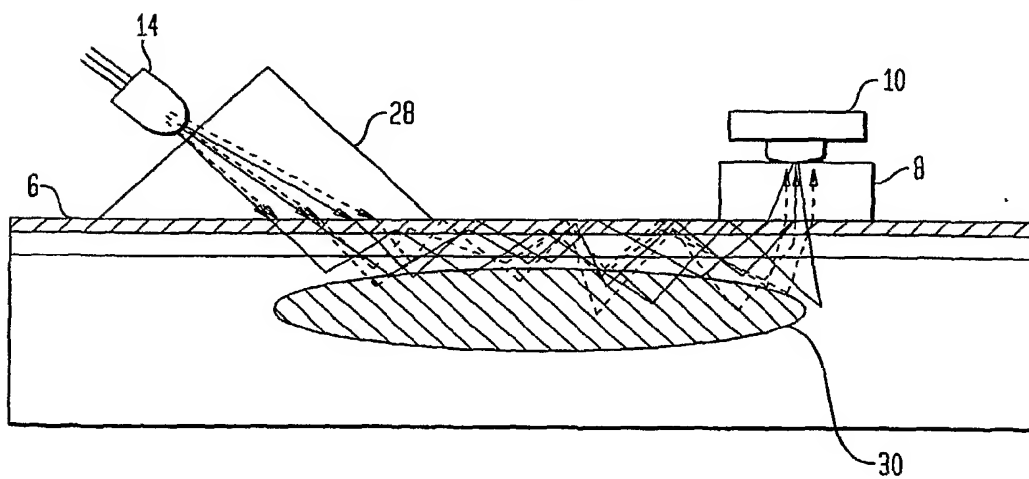
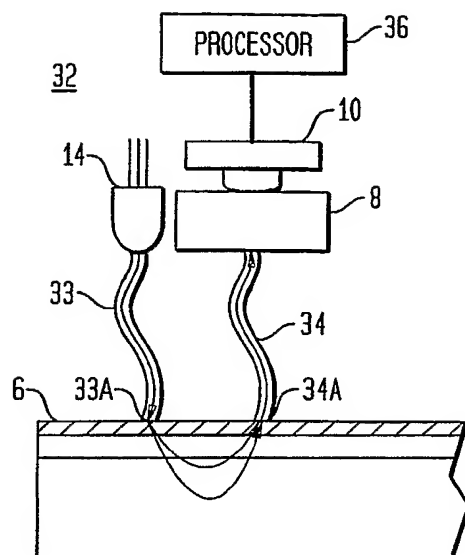
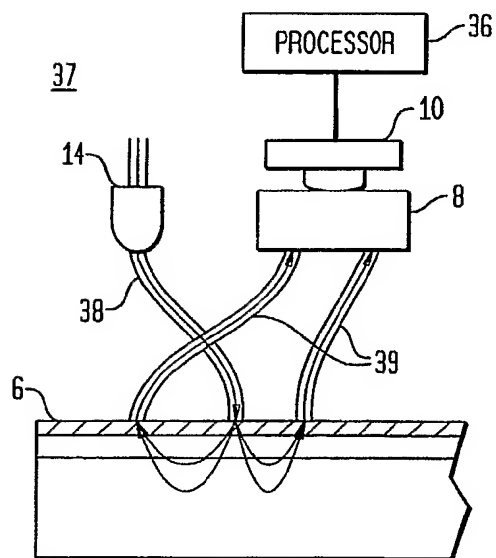


FIG. 10



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FIG. 11A**FIG. 11B**

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FIG. 11C

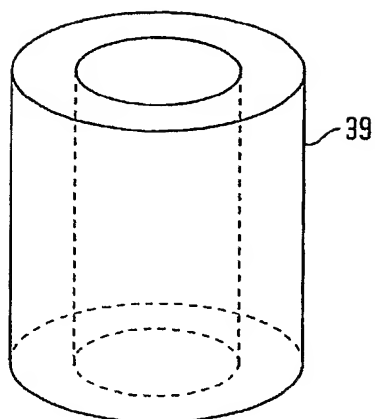
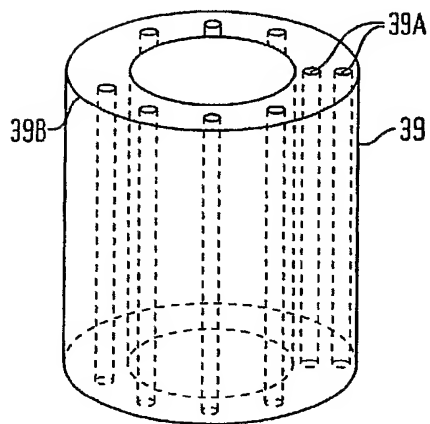


FIG. 11D



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FIG. 11E

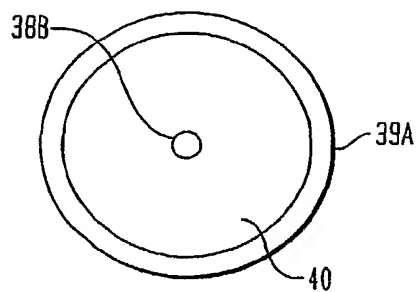
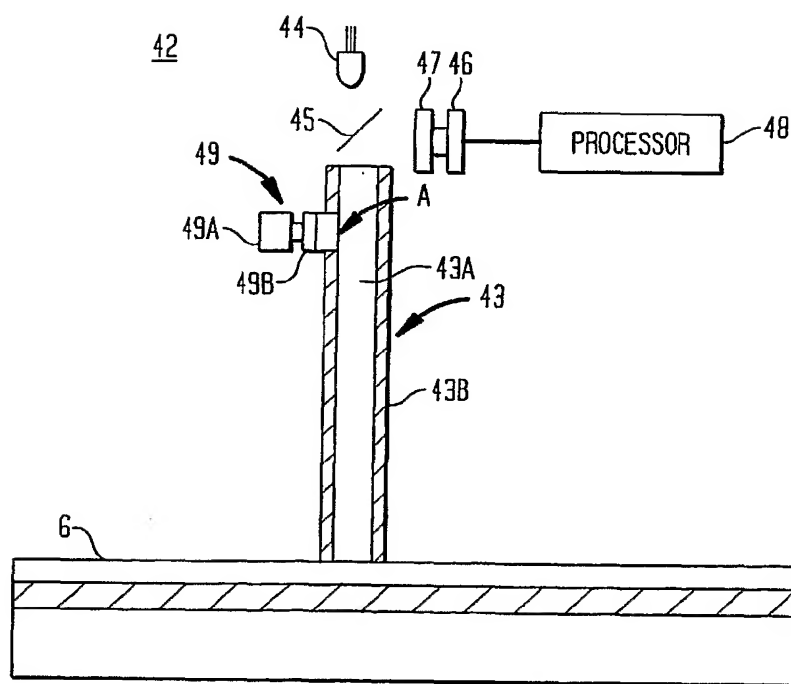


FIG. 12



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FIG. 13

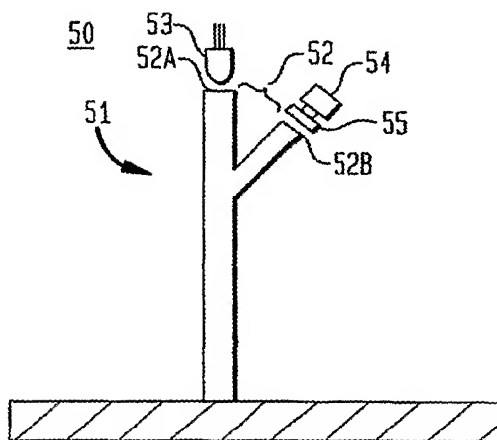


FIG. 14

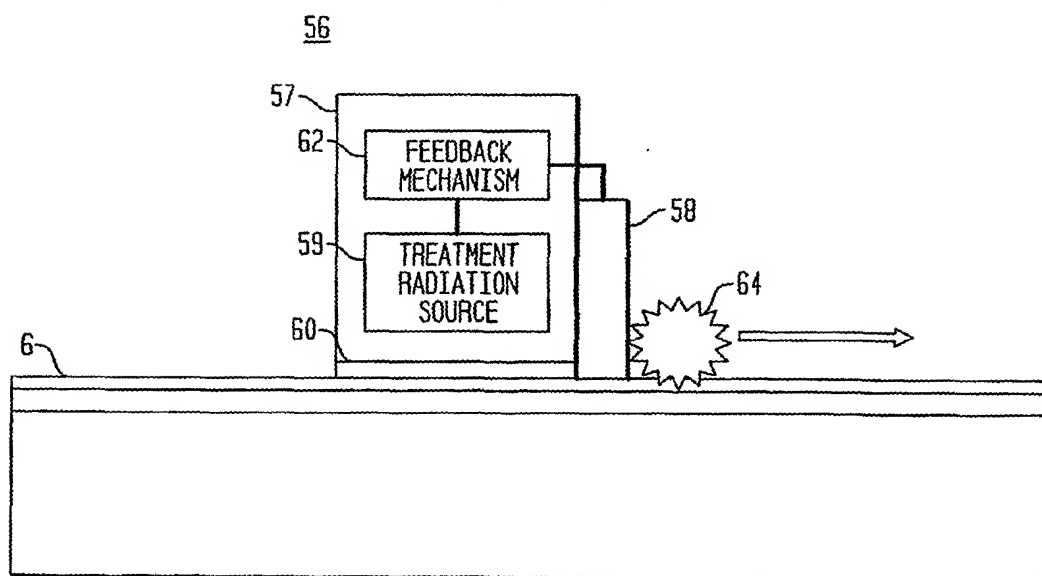
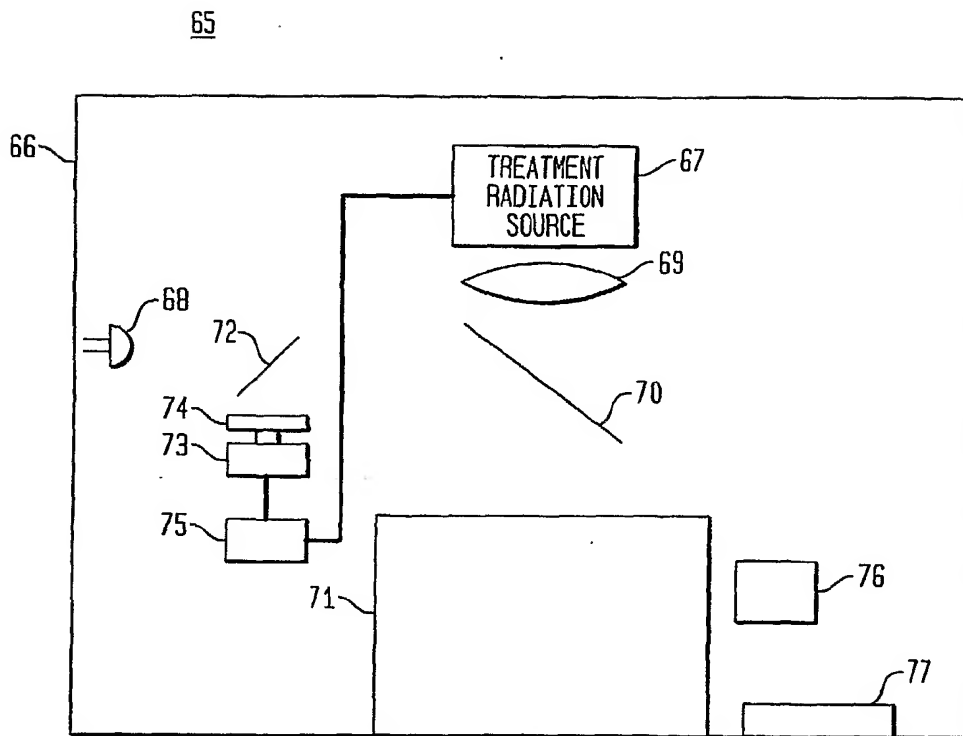


FIG. 15



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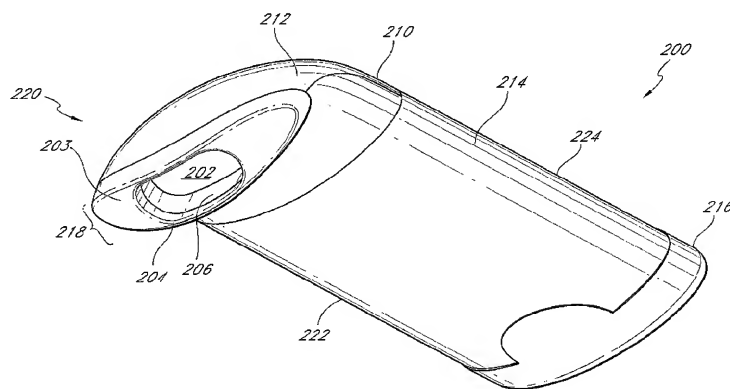
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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: LIGHT EMITTING THERAPEUTIC DEVICES AND METHODS



(57) Abstract: A light emitting device for providing therapy to a user includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface configured to be placed into contact with a treatment area on a user's body and configured to transmit the optical energy from the light source to the treatment area generally along a beam propagation axis. The user interface includes an electrical impedance sensor configured to determine when the user interface is contacting the treatment area. The device also includes a controller, configured to receive at least one sensor signal from the electrical impedance sensor, wherein the controller is configured to prevent activation of the light source based upon the at least one sensor signal.



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— *without international search report and to be republished
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LIGHT EMITTING THERAPEUTIC DEVICES AND METHODSCROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority from U.S. Provisional No. 60/873,559, filed December 6, 2006, which is incorporated by reference herein.

BACKGROUNDField

[0002] The disclosure generally relates to devices for treating skin conditions. For example, with respect to some embodiments, the disclosure relates to light-emitting devices and methods for the treatment of skin conditions including acne.

Description of the Related Art

[0003] Skin conditions can cause serious health risk including scarring and psychological damage. One of the most common skin conditions is acne, the most common form being acne vulgaris. Acne affects millions of people in the United States and is an inflammatory disease caused generally as a result of blockages in hair follicles. Acne affects the face and upper neck most commonly, but other areas of the body may also develop acne blemishes. While acne most commonly affects people during adolescence, it can affect people of all ages.

[0004] There is significant demand for skin treatment devices, particularly for those that treat acne. Several acne treatment methods are known including topical bactericidal products, topical antibiotics, oral antibiotics, hormonal treatments, topical retinoids and oral retinoids. Less common treatment methods include the use azelaic acid, zinc, tea tree oil, nicotinamide, and other agents. However, these products often have undesirable side effects, or have limited results.

[0005] Devices have also been used to treat acne, but the equipment is often large, expensive and difficult to use. There is therefore a need for a safe, user-friendly, hand-held, light emitting therapeutic device to treat skin conditions including acne.

SUMMARY

[0006] In one embodiment, a light emitting device for providing therapy to a user includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device also includes a user interface configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area generally along a beam propagation axis. The user interface includes an electrical impedance sensor configured to determine when said user interface is contacting said treatment area. The device also includes a controller, configured to receive at least one sensor signal from said electrical impedance sensor, wherein said controller is configured to prevent activation of said light source based upon said at least one sensor signal.

[0007] In various embodiments, the light source of may be a flashlamp or an LED. Moreover, the wavelength may be in a range of from about 400 nm to about 700 nm. The light emitting device may also include a transmission window configured to filter said optical energy prior to transmission to said treatment area.

[0008] The light emitting device may also include a second light source configured to generate second optical energy having a second wavelength. The second wavelength may be an infrared wavelength or a blue wavelength. The second light source may be an LED.

[0009] An aiming beam may also be included with the light emitting device, the aiming beam configured to illuminate the treatment area prior to activation of said light source. The light emitting device may further include a user input configured to activate said light source. The user input may include a button having a button depression axis, wherein said button depression axis is substantially aligned with said beam propagation axis. Said user interface may define a transmission pathway through an opening in said user interface, said user interface further including a locating ridge positioned at least partially around said opening and configured to provide tactile feedback to a user regarding the position of the opening. The locating ridge may extend around the entire opening.

[0010] In another embodiment, a light emitting device for providing therapy to a user includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface

configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area. The user interface defines a transmission pathway of said optical energy from said light source to said treatment area. The user interface includes a first contact sensor and a second contact sensor spaced apart from said first contact sensor. Moreover, a linear path from said first contact sensor to said second contact sensor at least partially traverses said transmission pathway.

[0011] The light emitting device may further include a controller configured to activate said light source only when both said first and second contact sensors are in contact with said treatment area. The first and second contact sensors may include first and second impedance sensors. Moreover, said light source may include a flashlamp. The device may further include a filter configured to filter said optical energy prior to delivery to said treatment area. Further, the device may include second light source configured to generate second optical energy having a second wavelength. The second light source may be an LED.

[0012] In another embodiment, a device light emitting device for providing therapy to a user includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area. The user interface may include an output window and at least two contact sensors. The device further includes a controller configured to determine an angular alignment between said output window and said treatment area prior to delivering optical energy to said treatment area.

[0013] The controller permits activation of said light source when said output window is determined to be substantially parallel to said treatment area. In one embodiment, said controller permits activation of said light source when said output window is determined to be inclined with respect to said treatment area no more than about 22 degrees.

[0014] The at least two contact sensors may include at least two impedance sensors. Moreover, the light emitting device may further include a second light source configured to generate blue light. The second light source may be an LED.

[0015] In another embodiment, a method of treating a physiological condition with optical energy includes providing a light emitting device, said light emitting device

including a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface configured to provide a transmission pathway of said optical energy from said light source to a treatment area generally along a beam propagation axis. The user interface includes an electrical impedance sensor. The device also includes a controller which is in electrical communication with said light source and electrical impedance sensor. The method further includes generating an impedance signal with said electrical impedance sensor and preventing generation of said optical energy when said impedance signal indicates that said user interface is not in contact with said treatment site.

[0016] Moreover, the method may further include generating said optical energy and directing said optical energy to said treatment area. The method may also further include filtering said optical energy prior to delivery to said treatment area. The filtering may remove energy having a wavelength outside of a range of from about 400 nm to about 700 nm.

[0017] The method may further include generating second optical energy with a second light source. The said second optical energy may include mostly infrared energy. The method may also include illuminating said treatment area with an illumination light source.

[0018] In another embodiment, a method of treating a physiological condition with optical energy includes providing a light emitting device. The light emitting device includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface configured to provide a transmission pathway of said optical energy from said light source to a treatment area. The user interface includes a first contact sensor and a second contact sensor spaced apart from said first contact sensor. A linear path from said first contact sensor to said second contact sensor at least partially traverses said transmission pathway. The method further includes determining a contact signal with said contact sensors, receiving a user input to activate said light source, and activating said light source in response to said contact signal and user input.

[0019] The activating step may include activating said light source when said contact signal indicates that said user interface is in contact with said treatment area and when said user input is activated. Receiving a user input may include determining if a button has been pressed or released.

[0020] The method may further include filtering said optical energy after activating said light source. The filtering step may remove energy having a wavelength outside of a range of from about 400 nm to about 700 nm. The method may further include generating second optical energy with a second light source. Moreover, said second optical energy may include mostly infrared energy. Finally, the method may further include illuminating said treatment area with an illumination light source prior to said activating.

[0021] In another embodiment, a method of treating a physiological condition with optical energy includes providing a light emitting device. The device includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. The device further includes a user interface, configured to transmit said optical energy from said light source to said treatment area. The user interface includes an output window, and at least two sensors. The method further includes receiving at least two sensor signals from said at least two sensors and determining an angular alignment between said output window and said treatment area based upon said at least two sensor signals.

[0022] The method may further include enabling activation of said light source in response to said angular alignment. The enabling step may occur only when said angular alignment indicates that said output window and said treatment area are substantially parallel. Moreover, said enabling may occur only when said angular alignment indicates that said output window and said treatment area are substantially in contact.

[0023] The method may further include illuminating said treatment area with an illumination light source where said light emitting device further include said illumination light source.

[0024] For purposes of summarizing the invention, certain aspects, advantages and novel features have been described herein. Of course, not necessarily all such aspects, advantages or features will be embodied in any particular embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other features will now be described with reference to the drawings summarized below. These drawings and the associated description are provided to illustrate certain embodiments, and not to limit the scope of the invention.

[0026] FIG. 1 is a block diagram of an acne treatment device according to an embodiment of the disclosure;

[0027] FIGS. 2A-C are front perspective, rear perspective and right side views, respectively, of an acne treatment device according to an embodiment of the disclosure;

[0028] FIGS. 3A-B are right side and top views, respectively, of an acne treatment device according to an embodiment of the disclosure;

[0029] FIGS. 4A-E are front perspective, right side, and three front perspective views, respectively, of several acne treatment devices according to various embodiments of the disclosure;

[0030] FIGS. 5A-B are cross-sectional views of output interfaces of an acne treatment device according to embodiments of the disclosure;

[0031] FIGS. 6A-E are front views of the head portion of an acne treatment device including safety mechanisms including sensor arrays according to various embodiments of the disclosure; and

[0032] FIGS. 7-10 show various embodiments of methods of treating acne with an acne treatment device according to various embodiments of the disclosure.

DETAILED DESCRIPTION

[0033] A light emitting therapeutic device 100 in accordance with one embodiment of the present disclosure is illustrated in **FIG. 1**. In one embodiment, the device 100 is a hand-held, ergonomically designed unit that allows a user to treat him or herself. The device 100 may also be described as a self-contained, hand-held, portable unit that is configured to be carried by a user. For example, in various embodiments, the device 100 is configured to be carried in the user's pant, shirt, or jacket pocket, or within a purse, handbag, or backpack.

[0034] In the illustrated embodiment, the device 100 includes a housing 110 that contains the device's internal components. The mechanical and electronic parts used to operate the device 100 are contained within the housing 110. In the illustrated embodiment, a light source 120, power source 130, processor 140 (sometimes referred to as a controller 140), user input interface 150, safety system 160, and output interface 170 are carried by or contained within the housing 110 of device the 100.

[0035] In some embodiments, light generated by the light source 120 and emitted from the device 100 has a wavelength configured or selected to penetrate the outer layers of skin sufficiently to cause a photo-dynamic effect that kills the P. Acnes bacteria and thereby treats acne. P. Acnes bacteria is one cause of acne. By destroying the bacteria, the device 100 removes acne blemishes from a user's skin. In some embodiments, light emitted from the device 100 penetrates the outer layers of the skin causing a thermal effect that kills the P. Acnes bacteria. In some embodiments, the photo-dynamic effect is the primary effect that leads to killing the P. Acnes bacteria. In other embodiments, the thermal effect is the primary effect. In yet other embodiments, the photo-dynamic and thermal effects are relatively equal.

[0036] FIGS. 2A-C illustrate another embodiment of the device 100. In some embodiments, the device 200 is the same as, or includes one or more of the same components of the device 100 described above with respect to FIG. 1. The device 200 includes a housing 210, which is configured to hold the device components. For example, the housing 210 can hold a light source, power source, controller, user interface, safety system, and/or output interface.

[0037] The housing 210 includes a head portion 212, a body portion 214, and a base portion 216. An output interface 218 (sometimes referred to as a user interface 218), is coupled to the housing 210 at the device's light-emitting end 220. In one embodiment, the portions 212, 214, 216 are removably attachable to one another. In other embodiments, the housing 210 is a single, molded, contiguous piece.

[0038] In other embodiments, the output interface 218, or portions thereof, are removably attachable to the housing 210. The removably attachable portions may be removed by using any of a variety of mechanisms, including friction mechanisms, such as friction locks, snaps, sliders, ridges, threads, etc., as well as other mechanical devices, including screws, locks, rings, etc.

[0039] The various segments or portions thereof that are removably attachable may be disposable. For example, the entire head portion 212, output interface 218, or portions thereof are disposable in some embodiments.

[0040] The housing 210 is ergonomically shaped and helps avoid fatigue during use. In some embodiments, for example the body portion 214 forms a handle region large enough accommodate a user's hand comfortably while allowing a firm grip. Moreover, in the

illustrated embodiment, the sides 222, 224 of the device 200 are rounded to comfortably accommodate the users thumb and fingers when gripping the device 200.

[0041] The housing 210 may be made of, for example, various types of metal, plastic, rubber, or a combination thereof. In some embodiments, the segments 212, 214, 216 of the housing 210 are made from different materials. For example, in some embodiments, the head portion 212 is made from plastic and the body portion 214 is made of metal, or vice versa.

[0042] In one embodiment, the device 200 includes a controller (not shown), such as the processor 140 described above with respect to FIG. 1. In one embodiment, the controller (or processor 140) is made from discrete logic only, and does not include a microprocessor or microcontroller. In such embodiments, the device 200 does not include any software or firmware. This advantageously helps simplify the electronics, reduces costs, and can greatly simplify design validation as well as regulatory review by agencies such as the Food & Drug Administration (the FDA).

[0043] In other embodiments, the controller (or processor 140) includes a controller, microcontroller, or memory, including a PIC microcontroller, embedded logic, a ROM, an EPROM, an EEPROM, a field-programmable gate array (FPGA), firmware or other programmable logic device (PLD). In other embodiments the controller (or processor 140) includes an ASIC, a soft microprocessor, or a complex programmable logic device (CPLD).

[0044] The controller controls operation of the device 200, as discussed in greater detail below. In general, wherever operation of the device 200 is discussed below, the controller may be the component which implements the operation even if not specifically mentioned with respect to the described operation.

[0045] In various embodiments, the controller includes a general purpose, single-chip or multi-chip microprocessor (such as a Pentium® processor, a Pentium® II processor, a Pentium® Pro processor, an x86 processor, an 8051 processor, a MIPS® processor, a Power PC® processor, or an ALPHA® processor). In addition, the controller may include a special purpose microprocessor, such as a digital signal processor.

[0046] The device 200 also includes a power source (not shown), which in some embodiments is the same as the power source 150 described above with respect to FIG. 1. The power source provides the power to operate the device 200. In some embodiments, the

power source includes a battery (such as a disposable or a rechargeable battery), a power cell, a fuel cell, and/or a capacitor. In some embodiments, the power source includes a single capacitor capable of holding the entire charge needed to power the device 200. In other embodiments, multiple, smaller capacitors are used. The power source generally includes capacitor charging and light source triggering circuitry, as well.

[0047] The power source may be physically located in any portion of the device 200. For example, in one embodiment, the power source is located in the base portion 216, which advantageously provides a counterbalance to the weight of the output interface 218 and provides easy access to a user. In one embodiment, the power source is disposable, such as a disposable battery. In other embodiments, the power source 130 is rechargeable, such as a lead and sulfuric acid, nickel cadmium (NiCd), nickel metal hydride (NiMH), lithium ion (Li-ion), or a lithium ion polymer (Li-ion polymer) battery).

[0048] The device 200 also includes a light source (not shown), which in some embodiments is the same as the light source 120 described above with respect to FIG. 1. In some embodiments, the light source is configured to emit a broad spectrum light. For example, the light source can include a flashlamp, such as a xenon or krypton gas filled flashlamp, or other broadband light source. Broadband light sources can be configured to emit light having wavelengths in the range of from about 400 nm to about 1100 nm.

[0049] In other embodiments, the light source is configured to emit monochromatic or substantially monochromatic light. For example, the light source can include an LED, diode, laser, or other narrow-band light source. In yet other embodiments, broad spectrum and monochromatic light is combined from one or more light sources, or alternated in their application from the device 200. In other embodiments, light of multiple wavelengths is emitted simultaneously or sequentially.

[0050] The output from the light source can be controlled or modulated prior to delivery to the user. For example, in some embodiments, the light emitted from the light source is passed through a filter. In one embodiment, the filtered light has a wavelength greater than 400 nm. The filtered light can have wavelengths in a range from about 400 nm to about 1100 nm, or from about 400 nm to about 700 nm. In other embodiments, the filtered light has a wavelength mostly at around 400 nm. The filter can be provided as an optical

coating to the light source (e.g., flashlamp), or as a window positioned between the light source and the user's treatment site.

[0051] In addition, the optical characteristics of the light generated by the light source can be controlled by the controller, or other electronic circuitry included with the housing 210. For example, by pulsing the light source, the emitted light's pulse shape can be modulated and controlled. In addition, by varying the drive current and/or voltage to the light source, the output power can be modulated or controlled.

[0052] In one embodiment, light emitted from the light source has a wavelength of about 400 nm. In other embodiments, the wavelength is greater than 400 nm. For example, in some embodiments, the wavelength is between about 400 and 700 nm. In other embodiments, the wavelength may be between 400 and 1100 nm. In some embodiments, the wavelength may be greater than 1100 nm. In one embodiment, the wavelength is in the blue spectrum, and the light emitted from the light source 120 is blue light.

[0053] As discussed above, the particular wavelength or range of wavelengths directed to a treatment site on a user can be controlled by using a narrow band light source configured to emit light at a desired wavelength (or range of wavelengths), or by using a broad band light source with filters to filter out or remove undesired light wavelengths.

[0054] In some embodiments, the light source includes both a broadband light source and a narrowband light source. For example, in one embodiment, the light source includes a flashlamps and one or more light emitting diodes (LEDs).

[0055] In another embodiment, the light source includes two flash lamps, each having a different optical coating configured to filter out different wavelengths. For example, in one embodiment, one coating is designed to transmit light in the infrared spectrum (or a portion thereof), and the other coating is designed to transmit light corresponding to the visible blue spectrum (or a portion thereof). In another embodiment, the two flashlamps are each housed in a different chamber within the housing 210, each chamber having a different filter window at its chamber output. In other embodiments, only one primary wavelength of light is transmitted through the optical coating, while in other embodiments, light having multiple primary wavelengths is transmitted therethrough.

[0056] In some embodiments, the wavelength or wavelengths transmitted to a treatment site are selectable; either automatically by the device 200 itself, or by the user via a

user interface (not shown). For example, in some embodiments, a user can select a desired treatment wavelength from a range using, for example, a series of buttons or a dial corresponding to a variety of wavelength ranges. Alternatively, the device 200 can include a digital user interface which allows a user to select a wavelength range or ranges from a menu displayed on a display. In some embodiments, the user selection will cause different types of optical filters to be placed in the path of the light source's output. In some embodiments, for example, a dial is mechanically coupled to an optical filter having different filtering materials on different sections, and turning the dial causes the filter material placed in the light path to change. In other embodiments, user selection causes the controller to actuate a motor or other device to move the desired filter into place.

[0057] The optical characteristic of the light emitted by light source may be varied as a function of skin pigmentation. For example, the variation may be based on the Fitzpatrick Classification Scale of skin pigmentation types. For example, when the user indicates that the device 200 is going to be used to treat a darker skin types, the controller will control the light source to generate pulsed optical energy having a longer pulse duration than when lighter skin type treatment is selected.

[0058] The optical characteristic may be automatically selected by the controller based on a user selection of skin pigmentation type, or by sensing the treatment site skin pigmentation. For example, the device 200 may include a dial or other form of user input interface to allow a user to set their skin pigmentation type. The controller could then, based on the user's skin pigmentation type, select the appropriate treatment pulse duration, peak power, average power, pulse interval, duty cycle, etc., and would actuate the flash lamp accordingly.

[0059] In other embodiments, the user selects the optical characteristic directly instead of selecting their pigmentation type and using the controller to determine optical characteristic. In yet other embodiments, the device 200 includes a colorimeter or other device to automatically determine the pigmentation of a user's treatment site. Furthermore, light emitted from the light source is sometimes characterized as an intense pulse of light. In some embodiments, the light source is removable from the device 200 by the user, either by hand, or with a tool.

[0060] In some embodiments, the light source includes a reflector to reflect, direct, and/or focus energy emitted from the light source towards the patient's skin. The reflector increases the amount of light received by the tissue and thereby increases the photo-therapeutic effect. In some embodiments the reflector has a parabolic cross sectional shape and extends along substantially the entire length of the light source. In other embodiments the reflector has a concave cross section.

[0061] Referring now to FIG. 3, in one embodiment, light generated by the light source is configured to travel along a beam propagation axis 300 as it travels through the transmission path 202 (sometimes referred to as a transmission channel 202, emission path 202, or emission channel 202) defined by the user interface 218. The light diverges as it travels along the propagation axis 300, thereby defining a beam propagation envelope 310.

[0062] Because the light diverges as it travels along the propagation axis 300, the light's energy density decreases as the distance from the light source to the treatment site increases. Therefore, to maximize energy density, the user interface 218 of the device 200 is brought into contact with the user's treatment site prior to activating the light source. When properly oriented, light generated by the light source will have an energy density in the range of from about 1 J/cm² to about 3 J/cm² (or from 1 J/cm² to 3 J/cm²) at the treatment site. In other embodiments, the energy density is in the range of about 1 J/cm² to about 10 J/cm² (or from 1 J/cm² to 10 J/cm²). In one embodiment, the energy density is about 6 J/cm².

[0063] In addition, in some embodiments, the light source delivers peak optical pulse power in the range of from about 5 kW to about 20 kW (or from 5 kW to 20 kW). In some embodiments, the light spot at the treatment site has an area of about 1 cm². In general, the light generated by the light source is safe to use near human eyes and will not cause serious or irreparable harm to the structures of the eye if it is accidentally discharged near or into the eye.

[0064] Referring to FIGS. 2A-3B, in one embodiment, the acne treatment device 200 also includes a user input 207 (which in some embodiments is the same as the user input interface 150 described above with respect to FIG. 1). The user input 207 for user control of various operational features. For example, in various embodiments, the user input 207 includes a switch, button (as illustrated), contact, and/or sensor. In some embodiments, the user input 207 causes the device 200 to turn on and/or off, to charge a power supply, to begin

or end light flashing, to program the exposure duration, and/or to enter a code to re-activate the device 200.

[0065] In the illustrated embodiment, button 207 causes the light source to first charge and then flash. In some embodiments there is a separate power mechanism such as a button or switch to turn on the device 200, while in other embodiments, a single button turns and activates the device 200.

[0066] For example, in some embodiments, the user presses the button 207 once in order to power on the device 200, which causes the flashing circuitry to charge. While the circuitry is charging, a status indicator 208 indicates that the device 200 is not ready to be activated. For example, during charging, the status indicator can illuminate to a red color. Once the flashing circuitry is charged, the status indicator 208 changes color to indicate that the device 200 is ready for use. For example, the status indicator changes to a green color.

[0067] Once charged and ready, pressing and releasing the button 207 cause the light source to flash and emit light. When the light source flashes, the flashing circuitry discharges through the light source, and the status indicator 208 again indicates that the device is not ready to be activated. The process can be repeated to deliver additional optical energy to a treatment site, or the device 200 may then be turned off. For example, the device 200 may be turned off by pressing and holding the button 207 for a specified duration.

[0068] In other embodiments, the user holds the button 207 to fully charge the flashing circuitry, e.g., until the status indicator 208 changes color from red to green. If the user releases the button prior to fully charging the flashing circuitry, the flashing circuitry will discharge, and light will not be generated from the light source. But if the flashing circuitry becomes fully charged, pressing (or pressing and releasing) the button 207 again causes the light source to activate.

[0069] In some embodiments, the device 200 includes an illumination light source (not shown) in addition to the therapeutic light source discussed above. The illumination light source may be located in or around the output interface 218 or on another portion of device 200. The illumination light source illuminates portions of the patient's skin in order to identify blemishes and problem areas for therapeutic treatment. The illumination source, for example, may include one or more LEDs, such as white light emitting LEDs. In some embodiments, the device 200 also includes an aiming or pointing mechanism (not shown),

such as an aiming beam, or a laser pointer. The aiming mechanism allows the user to more accurately identify problem areas and position and orient the device 200 prior to treatment.

[0070] In some embodiments the device 200 includes an aiming beam, an illumination source, or both. The aiming beam or illumination source may be activated by a separate button. For example, in some embodiments a button may be located on the side 222, 224 of the body portion 214 or head portion 212, such that it is accessible by the user's thumb. The user may activate the aiming beam or illumination source by depressing the button on the side with the thumb. Then the user may activate flash the device 200 using the button 207. In other embodiments, a partial depression of button 207 activates the aiming beam or illumination source and a full depression causes the device 200 to charge the flashing circuitry and activate the therapeutic light source.

[0071] Various aspects of the device 200 design provide intuitive use, and help the user orient the output interface 218 prior to activating the light source. This can be important for users that do not have access to a mirror during device 200 usage. For example, the arrangement of the button 207 with respect to the output interface 218 allows for beam propagation axis alignment with respect to a treatment area.

[0072] Referring again to FIGS. 3A and 3B, the button 207 may be pressed such that it moves along a button depression axis 320. The button depression axis 320 is substantially aligned with the beam propagation axis 310. This configuration advantageously allows a user to align the beam propagation axis with a treatment site by simply pointing at a desired treatment site or area with the finger used to press the button 207. Once aligned, the user may press the button 207 and to activate the light source, and to cause light from the light source to be directed to the treatment area.

[0073] Moreover, the general shape of device 200 allows for intuitive and ergonomic application of treatment. For example, the head portion's angulation 340, defined by the device's longitudinal axis 330 and beam propagation axis 300, allows for natural alignment of the users wrist and fingers when applying treatment to most areas of the body.

[0074] As discussed above, the device 200 includes an output interface 218 that serves as the interface between the device 200 and the treatment site, e.g., the user's skin. The output interface 218 can include a transmission surface, mirror, and/or window. In one

embodiment, the output interface 218 is disposable. In other embodiments, portions of the output interface 218 are disposable.

[0075] In the illustrated embodiment of FIGS. 2A, 2C, 3A, and 3B, the output interface 218 includes a surface 203 which is substantially orthogonal to the beam propagation axis 310. The surface 203 may contact the patient's skin and may be made of metal or plastic material. In some embodiments, the surface 203 is made of a soft rubber. In some embodiments, the surface 203 may be smooth so as to glide across the patient's skin.

[0076] The output interface 218 also includes an emission channel 202 through which the therapeutic light is emitted. As shown the emission channel 202 may have an oval shape cross-sectional shape. In other embodiments, the emission channel 202 may have a circular or rectangular cross-sectional shape.

[0077] In the illustrated embodiment, the therapeutic light generated by the light source travels through a transmission window 206 prior to exiting from the device 100. In some embodiments, the transmission window 206 is recessed from an output rim 204 as defined by emission channel 202 and surface 203. The transmission window 206 may be made of various optically-transparent materials including glass, quartz, fluorite or plastic, such as acrylic. The transmission window 206 may include an optical lens which refracts the emitted light to focus it onto a treatment area. Alternatively, the transmission window 206 may have a planar surface. In other embodiments, the transmission window 206 includes an optical coating to filter out undesirable wavelengths from broadband light generated by the light source.

[0078] Referring now to FIGS. 4A-E, in some embodiments, the output interface 218 includes a locating ridge 400 that extends from the surface 203 in the general direction of the beam propagation. As illustrated by FIG. 4A, the locating ridge 400 may be shaped to conform to the shape of the rim 204 defined by the emission channel 202. In one embodiment, the locating ridge 400 is made of a soft material, such as rubber, nylon, polyethylene, and/or expanded polytetrafluoroethylene (ePTFE). Certain materials, such as ePTFE, have low friction, lubricious qualities, that provide enhanced comfort to a user when placing the output interface 218 in contact with, and when moved against, the user's skin. The locating ridge 400 can be made from a soft material that conforms to the patient's features and/or blemishes as the device 200 moves across the skin. In other embodiments,

the locating ridge 400 is made of a plastic or metal. In one embodiment, the locating ridge 400 is made of an opaque material. The locating ridge 400 may therefore serve to increase the level of comfort associated with using the device 200, and also to act as a shield to limit, reduce, or prevent light from reaching the eyes of the user or others.

[0079] As shown in FIGS. 4A-C, the locating ridge 400 may be one contiguous member. In other embodiments, as illustrated by FIG. 4D and 4E, the locating ridge 400 may include multiple segments 401, 402, 403, 404. The embodiments illustrated in FIGS. 4D-E show configurations having two segments 401, 402 disposed vertically on the sides of the emission channel 202, and two segments 403, 404 disposed horizontally on the top and bottom of the emission channel 202, respectively. However, in other embodiments, there may be more than two segments arranged in different configurations. In one embodiment, locating ridge segments are provided on opposite sides of the emission channel 202.

[0080] As illustrated by FIG. 4A, the locating ridge 400 may extend along the entire rim 204 of the emission channel 202. Alternatively, in other embodiments, such as illustrated in FIG. 4C-E, the segment or segments may only cover or extend along a portion of the rim 204, leaving an opening. The opening or openings may serve to increase the level of comfort associated with using the device 200 by limiting the contact of the locating ridge 400 with sensitive blemishes when the device 200 is moved across the user's skin.

[0081] As illustrated by FIG. 5A, the transmission window 206 may be recessed or set back from surface 203 of the user interface 218 by a predetermined distance 502. In addition, the locating ridge 400 protrudes from output surface 203 a predetermined protrusion distance 500. When configured in this manner, the transmission window 206 is set back from the user's skin a total distance 501, which equals the sum of the predetermined distance 502 and the predetermined protrusion distance 500, when the device 200 is used.

[0082] In another embodiment, the locating ridge 400 is not provided, and the total distance 501 from the transmission window 206 to the user's skin (when the device 200 is used) is simply the predetermined distance 502. In yet other embodiments, as illustrated in FIG. 5B, the transmission window may be aligned flush with surface 203. As such, the total distance 501 from the transmission window 206 to the user's skin (when the device 200 is used) is simply the predetermined protrusion distance 500. In the configuration illustrated by

FIG. 5B, if no locating ridge 400 is present, transmission window is not set back from the user's skin at all, and makes direct contact to the user's skin (when the device 200 is used).

[0083] The arrangement of the output surface 203, the transmission window 206, the output rim 204 and the locating ridge 400 alone or together provide tactile information to the user when the device 200 is used. Tactile information advantageously helps the user determine the position and orientation of the device 200 prior to and during use.

[0084] In one embodiment, the emission channel 202 defines a large enough application area to completely surround the acne. In one embodiment, for example, the application area is 1 cm². Moreover, the user interface 218 may define one or more distances 500, 501, 502 between the surface 203 and transmission window 206 deep enough to envelope most blemishes. As the device 200 is moved across the user's skin the user will feel when blemishes are surrounded by the rim 204 and/or contained in the space defined by locating ridge 400. As such, the user will know when the device 200 is properly positioned with respect to a particular blemish to deliver a therapeutic treatment.

[0085] In some embodiments, the output interface 218 and/or various portions thereof (including the locating ridge 400) are removably attachable and or disposable. In some embodiments, for example, friction mechanisms may be used to allow for removable attachment. In other embodiments, latching mechanisms such as a latch and pocket type of mechanism may be employed. In other embodiments, an adhesive is used to attach the output interface 218 to the device 200, or to attach the locating ridge 400 to the output interface 218.

[0086] In another embodiment, the acne treatment device 200 includes a safety system, such as the safety system 160 described above with respect to FIG. 1. In one embodiment, the safety system includes circuitry and/or sensor that prevent light source activation until a safety condition is realized. For example, in some embodiments, the safety system includes a switch that is activated prior to enabling activation of the light source.

[0087] For example, the safety system can include, but is not limited to, a mechanical pressure switch, a contact switch, and/or an electrical switch such as a galvanic response, resistance or impedance switch. A galvanic response device is activated when brought into contact with a user's skin. The galvanic response device can prevent the device 200 from emitting light unless the device 200 is in contact with the user's skin. In addition,

the galvanic response device can prevent light from leaking or being emitted from the device 200 when activated, e.g., flashed.

[0088] Embodiments of safety switch arrangements are illustrated by FIGS. 6A-E. In the various embodiments, safety switch contacts 601-619 (sometimes referred to as sensors, or contact sensors) are arranged around the emission channel 202. In some embodiments, the contact arrangement is referred to as a contact array. For example, in the embodiment illustrated in FIG. 6A, two contacts 601, 602 are positioned arranged on opposite side of the emission channel 202. Until the patient's skin comes in contact the switch contacts 601, 602, the switch is open and the safety system 160 will not allow the device 100 to flash. Once the skin comes in contact with the contacts 601, 602 the switch will close and the user may activate the device 200 light source.

[0089] FIGS 6B-D illustrate contact configurations employing three, four and eight contacts, respectively. The dotted lines represent linear paths between various combinations of contacts, which when brought into contact with the user's skin, will close the safety switch and enable device 200 activation. For example, in FIG. 6C, the switch will close when either of two contact pairs 606, 609 or 607, 608 are brought into contact with the user's skin. In one embodiment, the linear paths at least partially traverse the emission channel 202 defined by the user interface 218. By assuring that such contacts are touching the user's skin prior to activation, the device 200 can determine whether the entire planar surface traversing the emission channel 202 is in contact with the user's skin, or if it is inclined at an angle with respect to the user's skin.

[0090] The dotted lines serve as possible combinations only and are not meant to limit the number of combinations possible in other embodiments. For example, in other embodiments, simultaneous contact with contacts 606 and 607 may also enable device 200 activation.

[0091] The embodiments of FIGS. 6A-D include contacts 601-614 having circular cross-sectional areas. However, in various embodiments, the safety switch contacts 601-614 may be shaped differently. For example, FIG. 6E illustrates a safety switch including crescent shaped contacts 618, 619 which are shaped to generally conform to the shape of window 202. contact shape can be selected to optimize user skin contact for a particular application.

[0092] As described above, in some embodiments, the safety switch includes various types of switches including analog- and digital-type electrical switches. The skin is an electrical conductor and therefore has a corresponding resistance. Therefore, the safety system can not only determine contacts are touching skin, but by analyzing the resistance measurements (or signals) obtained from various contacts, the safety system can determine the angle at which the user interface 218 is aligned or tilted with respect to a treatment area on the user's skin.

[0093] In other embodiments, the safety system uses the contact sensors or sensor arrays as digital switches. For example, in one embodiment, the safety system monitors the resistance between two contacts, and enables activation of the light source only when the resistance between the appropriate safety switch contacts falls beneath a certain threshold.

[0094] For example, with respect to FIG. 6A, when at least one of the contacts 601, 602 is not in contact with the skin, the resistance between the contacts 601, 602 is very large and the switch is open. In this situation, the device 200 will remain disabled by the safety system. However, when the contacts 601, 602 are both brought in contact with the skin, the resistance between them drops to an amount corresponding to resistance of the skin, and the switch will close. The safety system will cause activation, e.g. flashing, of the device 100 to be enabled. Moreover, in certain embodiments, the switch is configured to close when brought into contact with the skin but not when brought into contact with other conductive surfaces having different electrical characteristics.

[0095] One advantage of using electrical impedance sensors as contact sensors is that the safety system cannot be fooled into thinking that it is in contact with skin by merely pressing down on a mechanical switch. This functionality improves device 200 safety, as it prevents the device 200 from being activated when not contacting skin, which could lead to light emission into a user's or other party's eyes. Product safety is further enhanced by providing two or more sensors, as discussed above.

[0096] In other embodiments, the safety switch includes mechanical switches, such as a mechanical pressure switch that closes when a certain amount of pressure is detected by the switch. For example, with respect to FIG. 6A, if a certain threshold pressure is placed on the contacts 601, 602, the switch closes, and the safety system 160 causes activation, of the device 200.

[0097] The illustrated embodiments include multiple contacts 601-619, at least two of which are in contact with the skin to enable activation of the device 200. However, in other embodiments, there may be only one contact or only one contact may need to be in contact with the skin to enable activation of the device. For example, in certain embodiments, a single contact may be placed along rim 204 or locating ridge 400 or portions thereof. Moreover, while the illustrated embodiments show the contact or contacts 601-619 disposed on the surface 203, in other embodiments, the contact or contacts 601-619 may be located in various other portions of output interface 218. For example, the contact or contacts 601-619 may be located underneath the surface 203, on the rim 204, or on or within locating ridge 400.

[0098] In various embodiments, the acne treatment device 200 is configured to limit operability to a predetermined event. For example, the device 200 is generally configured such that is not usable after a certain amount of time, light exposure, light pulses, activations, etc. After the predetermined event occurs, the device 200 can be re-activated. For example, in some cases, the device 200 is re-activated by entering a validation code, or by replacing a part, such as the light source or power supply. In other embodiments, the device 200 is re-activated by downloading an activation code or activation signal from a remote location, such as over the Internet.

[0099] In one embodiment, the controller is configured to limit operability of the optical device 200. For example, the controller can be configured to prevent the optical device 200 from emitting light after a predetermined event. In one embodiment, the controller prevents optical device 200 operation after a predetermined number of light flashes, or light emissions are produced (e.g., 50, 100, 250, 500, or 1000 light flashes). In other embodiments, the controller prevents optical device 200 operation after a predetermined time of total light emission (e.g., 5, 10, 15, 30, 60, or 120 minutes). In other embodiments, the controller prevents optical device 200 operation after a predetermined event, such as a predetermined number of device-to-skin contacts (e.g., 50, 100, 250, 500, or 1000 contacts).

[0100] In general, the lifetime of the light source can be predetermined and/or set to expire after a preset number of flashes, by mechanical and/or electronic operations, including software and firmware. Such software and/or firmware can be included in the

device 200, controller, and/or housing 210. In one embodiment, after reaching the preset maximum number of flashes, the device 200 is re-activated by removing the light source and replacing it with a new light source.

[0101] In other embodiments, the device 200 includes an audible signal that warns the user that the system is ready to flash. If within a preset period of time the unit is not placed on to the skin so that the pressure/contact switch is activated the unit discharges, and the flash charge is lost.

[0102] In other embodiments, the device 200 includes a timer, such as a timing circuit. The timer is configured to prevent rapid flashing by the user. For example, the timer can provide a delay of about 1, 5, 10, 30, or more than 30 seconds between flashes or light emissions from the light source. The timing circuit can be provided as discrete circuitry and/or implemented with the controller.

[0103] In other embodiments, the device 200 includes an indicator, such as an LED, display, icons, microphone, and/or other indicator. In one embodiment, the device 200 emits an audible signal that warns the user that the power is too low on the unit to use.

[0104] In other embodiments the device 200 includes at least one security device capable of determining whether the device 200 remains a compliant device. For example, the security device may be configured to assist in the determination of whether the power source, light source or output interface 218 are compliant with device 200. The security device may be, for example, a 20K EEPROM well known to those of skill in the art and capable of performing various diagnostic and control functions.

[0105] FIG. 7 shows one embodiment of using an acne treatment device. A power button is pressed to turn on the device at step 710. The device is then turned on at step 720. The method then determines if a re-activation of the device is required at step 730. For example, the device determines if a predetermined number of light flashes have already been provided by the device. If so, the device indicates that re-activation is required at step 731, and then stops by turning the device off at 732. Use of the device and light source is prevented.

[0106] However, if not, the method charges the power supply at step 740. For example, the method charges a capacitor. When charged, the method indicates that the device is ready to be used. The method waits until a user input interface is actuated at step

750. For example, the method waits until the user presses button 207. Prior to actuation, the method monitors the power button to determine if it is pressed again at step 751. If so, the device discharges the power supply and shuts off at step 750.

[0107] Otherwise, when the user input interface is actuated, the method checks to see if the safety system is in safe mode at step 760. For example, the method checks to see if the appropriate contacts of the safety switch are in contact with the user's skin. If not, the method waits until the unit is in safe mode and the user input interface is actuated again at step 750. If so, the method causes the device to emit a therapeutic light dosage to the user's skin through the output interface at step 770. After the light is emitted, the method returns to step 730 to determine whether re-activation of the device is required.

[0108] FIG. 8 shows a method 800 of treating acne with an acne treatment device according to an embodiment of the disclosure. The method 800 begins at step 810, in which a light emitting device is provided. The light emitting device is the device 100 described above with respect to FIG. 1. In other embodiments, the light emitting device is the device 200 described above with respect to FIG. 2, or some other light emitting device. The light emitting device includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. In some embodiments, the light source is the light source 120, described above with respect to FIG. 1, or another light source.

[0109] The device provided by method 800 further includes a user interface configured to provide a transmission pathway for the optical energy from the light source to a treatment area generally along a beam propagation axis. The transmission pathway may be, for example, transmission path 202, described above with respect to FIG. 2. For example, in some embodiments, the user interface may be the user interface 150 described above with respect to FIG. 1, the user interface 218 described above with respect to FIG. 2, or some other user interface. The user interface includes an electrical impedance sensor, such as, for example, any of the electrical impedance sensors described above, or some other impedance sensor. In other embodiments, the impedance sensor may be another impedance sensor. The device also includes a controller, for example, processor 140 described above with respect to FIG. 1, which is in electrical communication with the light source and electrical impedance sensor.

[0110] The method 800 includes generating an impedance signal with the electrical impedance sensor at step 820. At decision step 830, the method 800 determines whether the user interface is in contact with the treatment site. If the user interface is in contact with the treatment site, the method 800 allows activation of the light source and generation of the optical energy at step 840. The method 800 then returns to step 820. On the other hand, if at step 830 the method 800 determines that the user interface is not in contact with the treatment site, the method 800 prevents activation of the light source at step 850. The method 800 then returns to step 820.

[0111] The method 800 may include additional steps not shown in FIG. 8. For instance, the method 800 may include activating the light source, generating the optical energy and directing the optical energy to a treatment area. The method 800 may further include filtering the optical energy prior to delivery to the treatment area. The filtering step may include removing energy having a wavelength outside of a range of from about 400 nm to about 700 nm or by removing energy having a wavelength below about 400 nm. In other embodiments, the method 800 also includes generating additional optical energy with a second light source. The additional optical energy may include mostly infrared energy. Method 800 may further include illuminating the treatment area with an illumination light source, such as, for example, any of the illumination light sources described above.

[0112] FIG. 9 shows a method 900 of treating acne with an acne treatment device according to an embodiment of the disclosure. The method 900 begins at step 910, in which a light emitting device is provided. The light emitting device may be the device 100 described above with respect to FIG. 1, the light emitting device 200 described above with respect to FIG. 2, or some other light emitting device. The light emitting device includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. In some embodiments, the light source is the light source 120, described above with respect to FIG. 1, or another light source.

[0113] The acne treatment device further includes a user interface configured to provide a transmission pathway of the optical energy from the light source to a treatment area generally along a beam propagation axis. For example, in some embodiments, the user interface may be the user interface 150 described above with respect to FIG. 1, the user interface 218 described above with respect to FIG. 2, or some other user interface. The user

interface is configured to provide a transmission pathway of the optical energy from a light source to a treatment area and includes at least a first and second contact sensor spaced apart from each other. The transmission pathway may be, for example, transmission path 202, described above with respect to FIG. 2. A linear path from the first contact sensor to the second contact sensor at least partially traverses the transmission pathway. For example, in some embodiments, the contact sensors are the contact sensors described above with respect to FIGS 6A-6E. For example, with respect to FIG. 6A, the first and second contact sensors may be contacts 601, 602. Moreover, in one embodiment, the linear path is the linear path represented by the dashed line of FIG. 6A.

[0114] The method 900 further includes determining a contact signal with the contact sensor information provided by the first and second contact sensors at step 920. The method 900 then receives user input at step 930 indicating that the user is attempting to activate the light source. For example, the user input may be the user pressing button 207 or some other button or user input mechanism. At decision step 940 the method 900 determines whether a contact condition is met. For example, the method 900 uses the contact signal to determine whether the first and second contact sensors defining the linear path are in contact with the treatment area. If the contact condition is met, the device allows light source activation at step 950. The method 900 then returns to step 920. On the other hand, at step 960, if the contact condition is not met, the method 900 prevents activation of the light source. The method 900 then returns to step 920.

[0115] The method 900 may include additional steps not shown in FIG. 9. For instance, the method 900 may include activating the light source when the contact signal indicates that contact condition is met. The method 900 may further include receiving a user input to determine if a button has been pressed or released. The method 900 may also include filtering optical energy after activating the light source. The filtering step may include removing energy having a wavelength outside of a range of from about 400 nm to about 700 nm, or removing energy having a wavelength below about 400 nm. In other embodiments, the method 900 also includes generating additional optical energy with a second light source. The additional optical energy may include mostly infrared energy. The method 900 may further include illuminating the treatment area with an illumination light source prior to activating the light source.

[0116] FIG. 10 shows a method 1000 of treating acne with an acne treatment device according to another embodiment of the disclosure. The method 1000 begins at step 1010, in which a light emitting device is provided. The light emitting device includes an output window. The output window may be any of the output windows described above, or another output window. The light emitting device may be the device 100 described above with respect to FIG. 1, the light emitting device 200 described above with respect to FIG. 2, or some other light emitting device. The light emitting device includes a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm. In some embodiments, the light source is the light source 120, described above with respect to FIG. 1, or another light source.

[0117] The device further includes a user interface configured to provide a transmission pathway of said optical energy from said light source to a treatment area generally along a beam propagation axis. For example, in some embodiments, the user interface may be the user interface 150 described above with respect to FIG. 1, the user interface 218 described above with respect to FIG. 2, or some other user interface. The user interface includes at least two sensors.

[0118] At step 1020 the method 1000 receives at least two sensor signals from the sensors. The sensors may be any of the sensors described above or other sensors. Based on the sensor signals, the method 1000 determines the angular alignment between the output window and a treatment area at step 1030. At decision step 1040, the method 1000 determines whether an angular alignment condition is met. For example, the method 1000 determines whether the device is substantially parallel to the surface of the treatment area. In another embodiment, the method 1000 may determine if the output window and treatment area are substantially in contact or if the angle between them is less than a predetermined value. If the angular alignment condition is met, the method 1000 allows activation of the light source at step 1050. The method then returns to step 1020. On the other hand, if the angular alignment condition is not met, the method 1000 prevents light source activation at step 1060. The method then returns to step 1020. The method 1000 may further include illuminating the treatment area with an illumination light source. The illumination light source may include any of the illumination light sources described above.

[0119] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. Moreover, the described embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms without departing from the spirit thereof. Accordingly, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein.

WHAT IS CLAIMED IS:

1. A light emitting device for providing therapy to a user, comprising:
 - a light source, configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm;
 - a user interface, configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area generally along a beam propagation axis, wherein said user interface comprises an electrical impedance sensor configured to determine when said user interface is contacting said treatment area; and
 - a controller, configured to receive at least one sensor signal from said electrical impedance sensor, wherein said controller is configured to prevent activation of said light source based upon said at least one sensor signal.
2. The light emitting device of Claim 1, wherein said light source comprises a flashlamp.
3. The light emitting device of Claim 1, wherein said light source comprises an LED.
4. The light emitting device of Claim 1, wherein said wavelength is in a range of from about 400 nm to about 700 nm.
5. The light emitting device of Claim 1, further comprising a transmission window configured to filter said optical energy prior to transmission to said treatment area.
6. The light emitting device of Claim 1, further comprising a second light source configured to generate second optical energy having a second wavelength.
7. The light emitting device of Claim 6, wherein said second wavelength comprises an infrared wavelength.
8. The light emitting device of Claim 6, wherein said second wavelength comprises a blue wavelength.
9. The light emitting device of Claim 6, wherein the second light source comprises an LED.
10. The light emitting device of Claim 1, further comprising an aiming beam, configured to illuminate the treatment area prior to activation of said light source.

11. The light emitting device of Claim 1, further comprising a user input configured to activate said light source.
12. The light emitting device of Claim 11, wherein said user input comprises a button having a button depression axis, wherein said button depression axis is substantially aligned with said beam propagation axis.
13. The light emitting device of Claim 1, wherein said user interface defines a transmission pathway through an opening in said user interface, said user interface further comprises a locating ridge positioned at least partially around said opening and configured to provide tactile feedback to a user regarding the position of the opening.
14. The light emitting device of Claim 13, wherein said locating ridge extends around the entire opening.
15. A light emitting device for providing therapy to a user, comprising:
 - a light source, configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm; and
 - a user interface, configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area, said user interface defining a transmission pathway of said optical energy from said light source to said treatment area,
 - wherein said user interface comprises a first contact sensor and a second contact sensor spaced apart from said first contact sensor, and
 - wherein a linear path from said first contact sensor to said second contact sensor at least partially traverses said transmission pathway.
16. The light emitting device of Claim 15, further comprising a controller, wherein said controller is configured to activate said light source only when both said first and second contact sensors are in contact with said treatment area.
17. The light emitting device of Claim 15, wherein said first and second contact sensors comprise first and second impedance sensors.
18. The light emitting device of Claim 15, wherein said light source comprises a flashlamp.
19. The light emitting device of Claim 15, further comprising a filter configured to filter said optical energy prior to delivery to said treatment area.

20. The light emitting device of Claim 15, further comprising a second light source configured.

21. The light emitting device of Claim 20, wherein said second light source comprises an LED.

22. A light emitting device for providing therapy to a user, comprising:

a light source, configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm; and

a user interface, configured to be placed into contact with a treatment area on a user's body and configured to transmit said optical energy from said light source to said treatment area, said user interface comprising an output window, and at least two contact sensors; and

a controller, configured to determine an angular alignment between said output window and said treatment area prior to delivering optical energy to said treatment area.

23. The light emitting device of Claim 22, wherein said controller permits activation of said light source when said output window is determined to be substantially parallel to said treatment area.

24. The light emitting device of Claim 22, wherein said controller permits activation of said light source when said output window is determined to be inclined with respect to said treatment area no more than about 22 degrees.

25. The light emitting device of Claim 22, wherein said at least two contact sensors comprise at least two impedance sensors.

26. The light emitting device of Claim 22, further comprising a second light source configured to generate blue light.

27. The light emitting device of Claim 26, wherein said second light source comprises an LED.

28. A method of treating a physiological condition with optical energy, comprising:

providing a light emitting device, said light emitting device comprising:

a light source configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm;

a user interface configured to provide a transmission pathway of said optical energy from said light source to a treatment area generally along a beam propagation axis, wherein said user interface comprises an electrical impedance sensor; and

a controller, in electrical communication with said light source and electrical impedance sensor;

generating an impedance signal with said electrical impedance sensor; and

preventing generation of said optical energy when said impedance signal indicates that said user interface is not in contact with said treatment site.

29. The method of Claim 28, further comprising generating said optical energy and directing said optical energy to said treatment area.

30. The method of Claim 29, further comprising filtering said optical energy prior to delivery to said treatment area.

31. The method of Claim 30, wherein said filtering removes energy having a wavelength outside of a range of from about 400 nm to about 700 nm.

32. The method of Claim 29, further comprising generating second optical energy with a second light source.

33. The method of Claim 32, wherein said second optical energy comprises mostly infrared energy.

34. The method of Claim 29, further comprising illuminating said treatment area with an illumination light source.

35. A method of treating a physiological condition with optical energy, comprising:

providing a light emitting device, comprising:

a light source, configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm; and

a user interface configured to provide a transmission pathway of said optical energy from said light source to a treatment area, wherein said user interface comprises a first contact sensor and a second contact sensor spaced apart from said first contact sensor, wherein a linear path from said first

contact sensor to said second contact sensor at least partially traverses said transmission pathway;
determining a contact signal with said contact sensors;
receiving a user input to activate said light source; and
activating said light source in response to said contact signal and user input.

36. The method of Claim 35, wherein said activating comprises activating said light source when said contact signal indicates that said user interface is in contact with said treatment area and when said user input is activated.

37. The method of Claim 35, wherein said receiving a user input comprises determining if a button has been pressed or released.

38. The method of Claim 35, further comprising filtering said optical energy after activating said light source.

39. The method of Claim 38, wherein said filtering removes energy having a wavelength outside of a range of from about 400 nm to about 700 nm.

40. The method of Claim 35, further comprising generating second optical energy with a second light source.

41. The method of Claim 40, wherein said second optical energy comprises mostly infrared energy.

42. The method of Claim 35, further comprising illuminating said treatment area with an illumination light source prior to said activating.

43. A method of treating a physiological condition with optical energy, comprising:

providing a light emitting device, comprising:

a light source, configured to generate optical energy having a wavelength in a range of from about 400 nm to about 1100 nm; and

a user interface, configured to transmit said optical energy from said light source to a treatment area, said user interface comprising an output window, and at least two sensors; and

receiving at least two sensor signals from said at least two sensors;

determining an angular alignment between said output window and said treatment area based upon said at least two sensor signals.

44. The method of Claim 43, further comprising enabling activation of said light source in response to said angular alignment.

45. The method of Claim 44, wherein said enabling occurs only when said angular alignment indicates that said output window and said treatment area are substantially parallel.

46. The method of Claim 44, wherein said enabling occurs only when said angular alignment indicates that said output window and said treatment area are substantially in contact.

47. The method of Claim 43, further comprising illuminating said treatment area with an illumination light source, wherein said light emitting device further comprises said illumination light source.

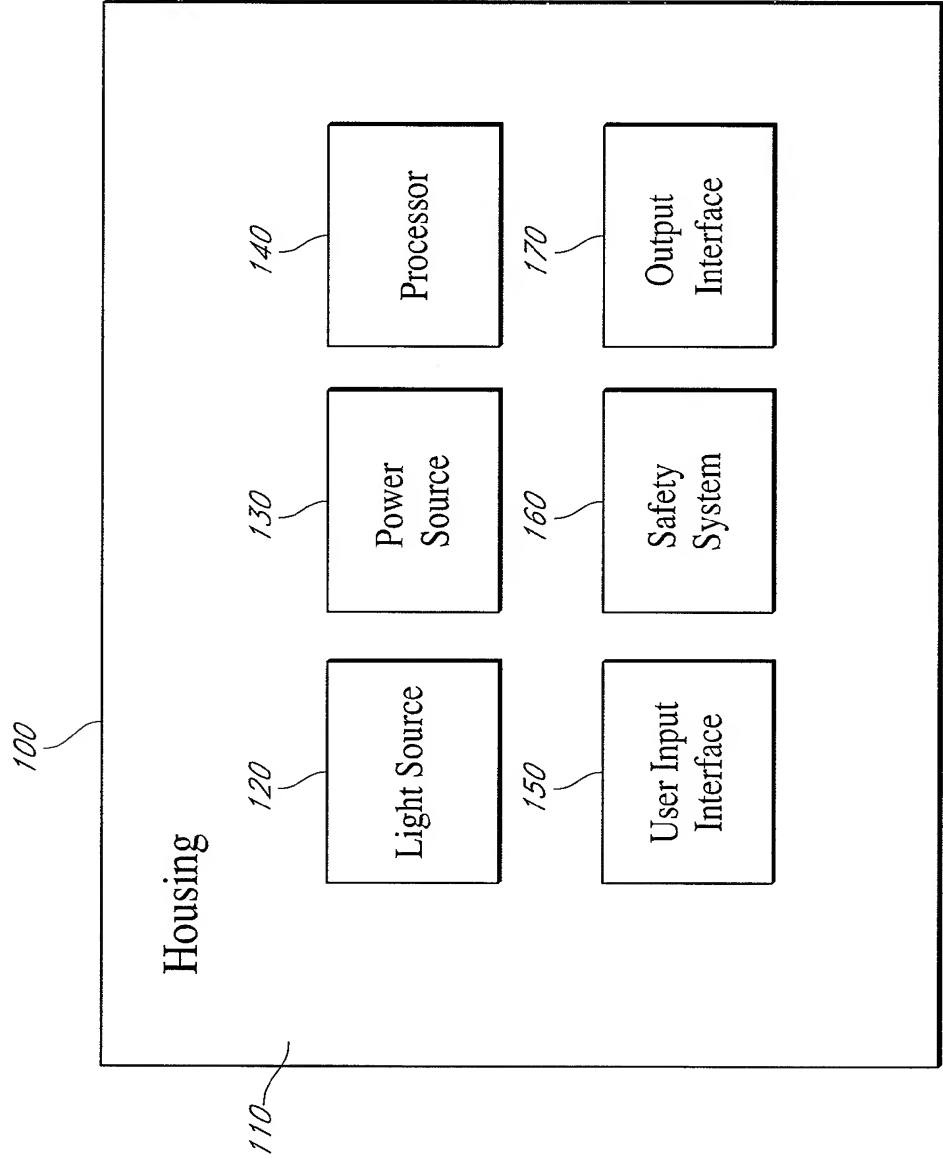


FIG. 1

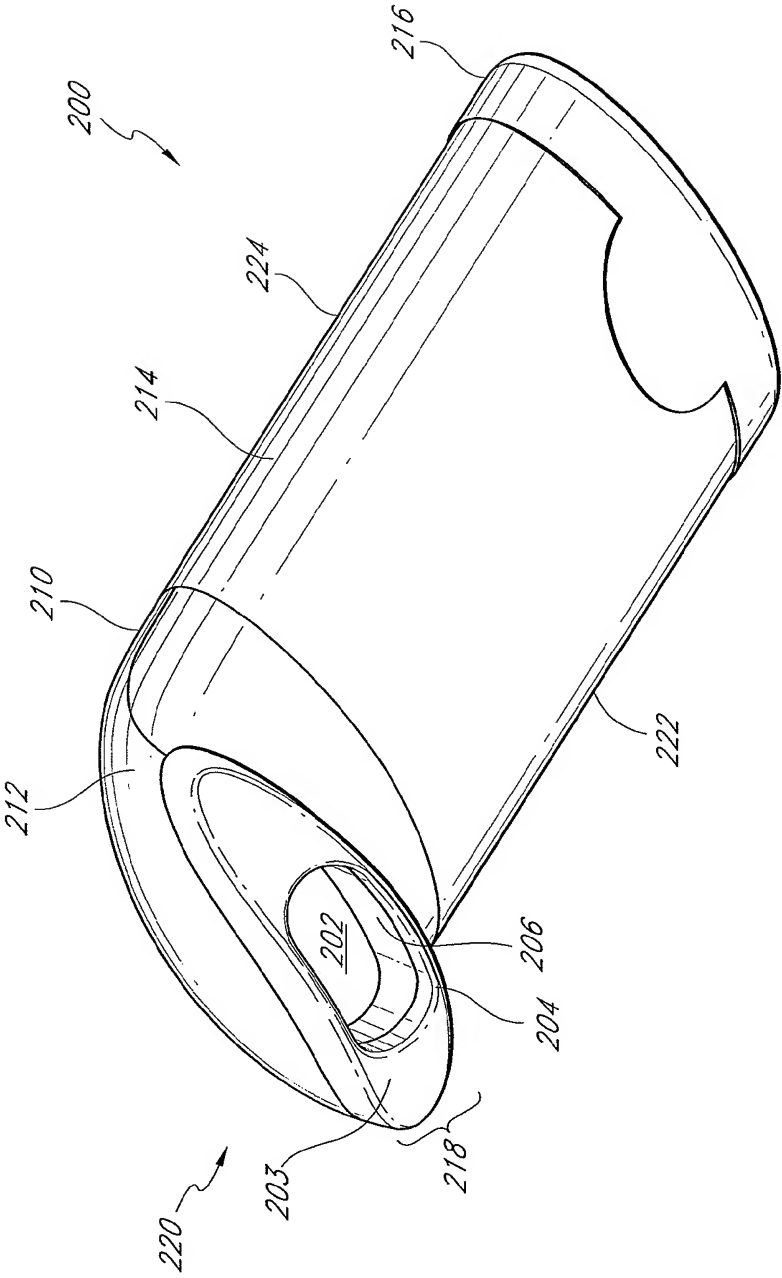


FIG. 2A

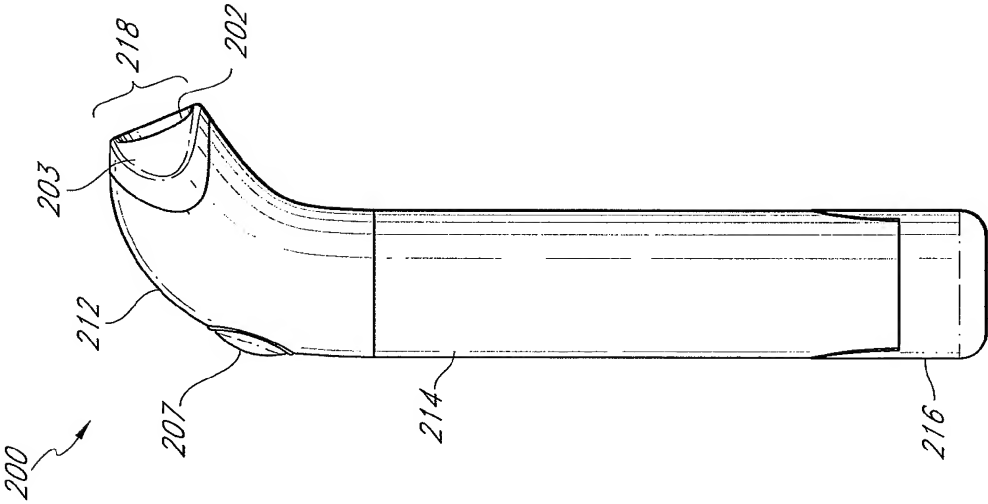


FIG. 2C

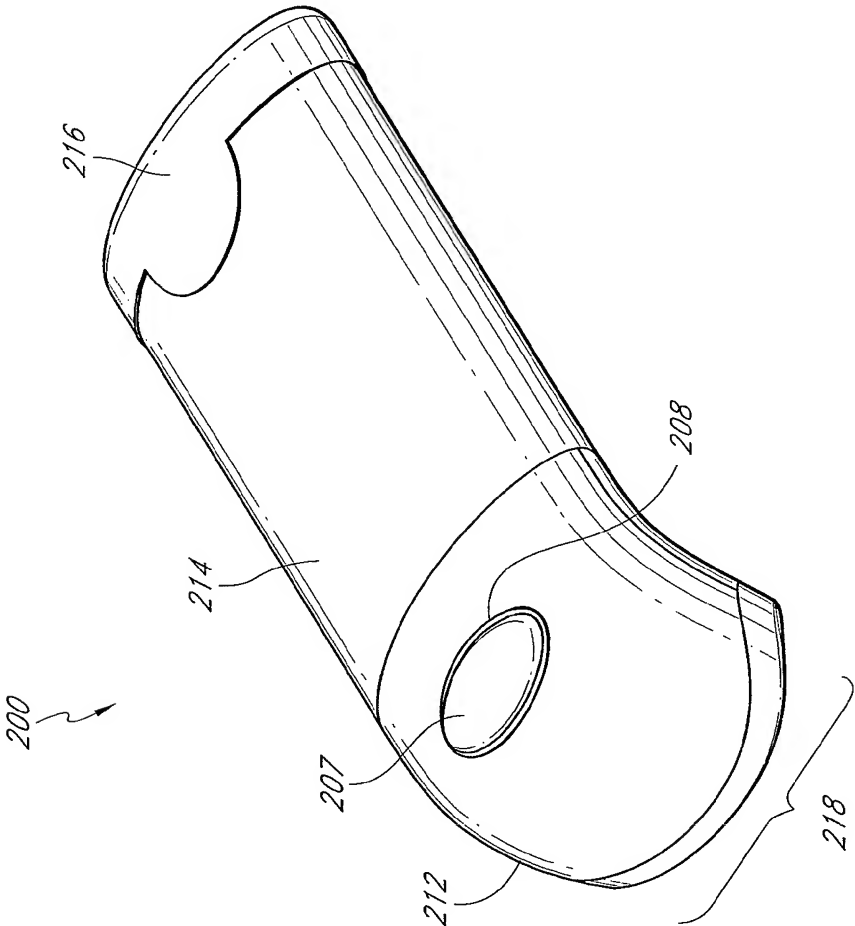


FIG. 2B

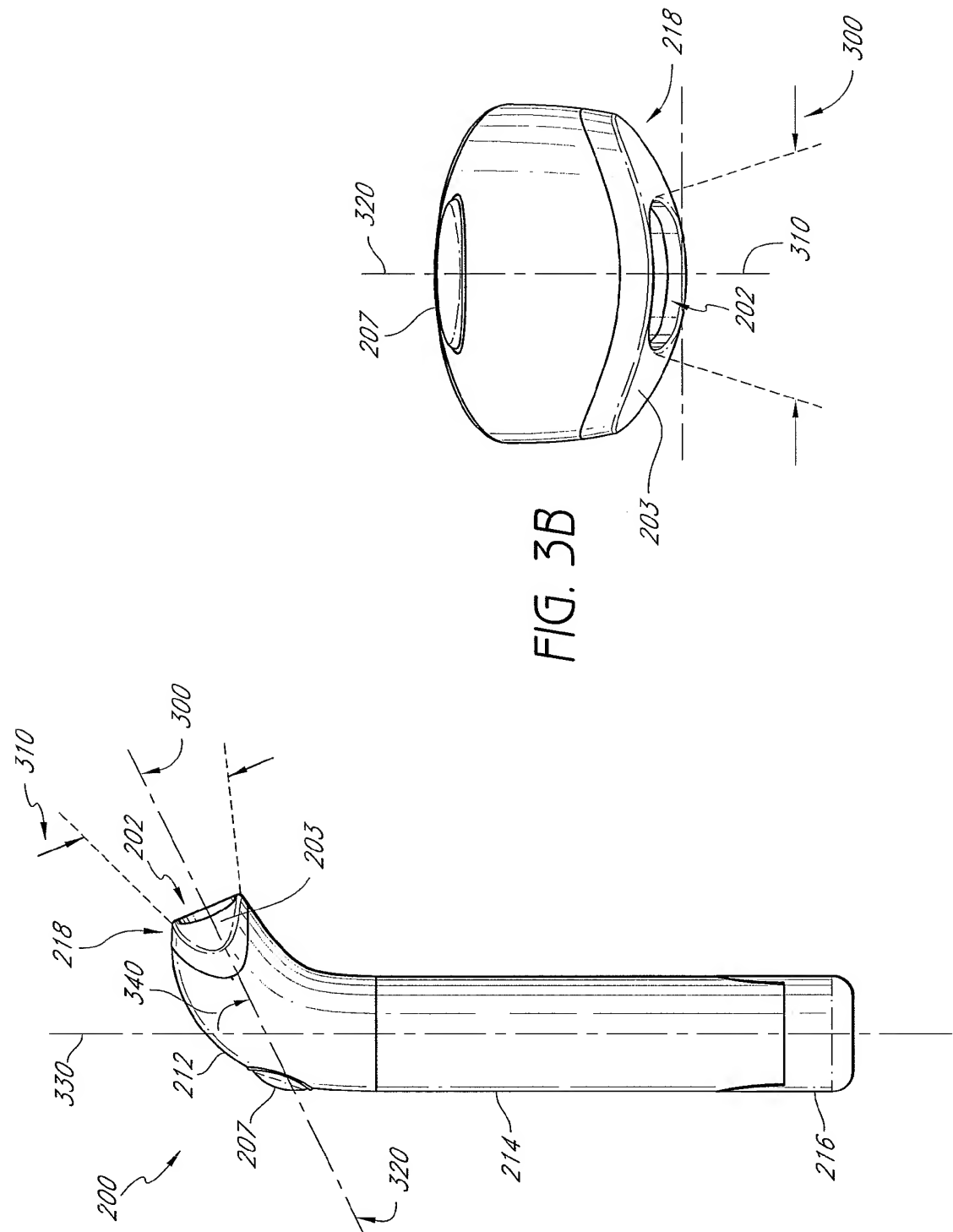


FIG. 3B

FIG. 3A

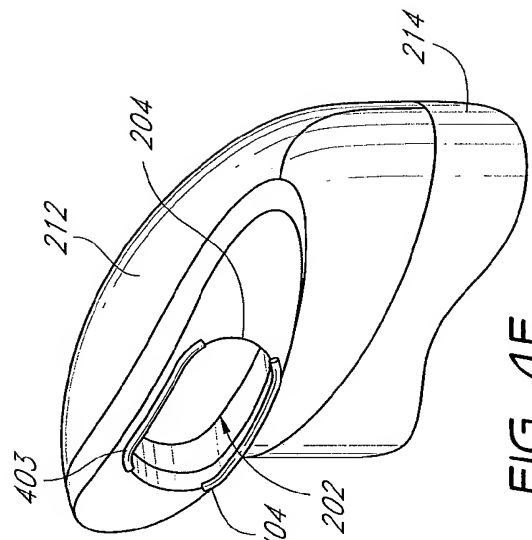
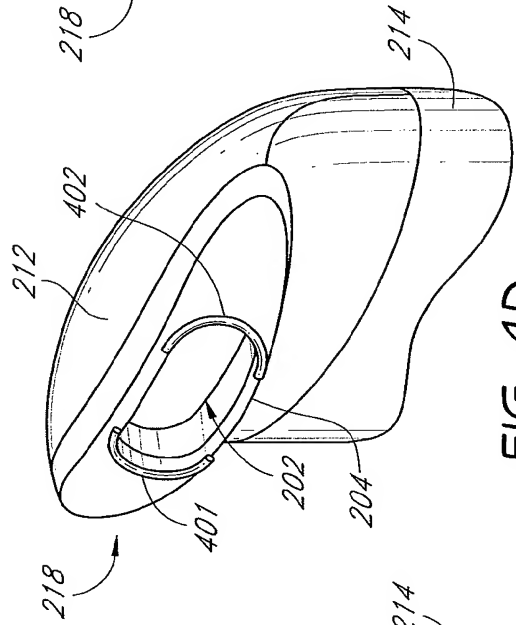
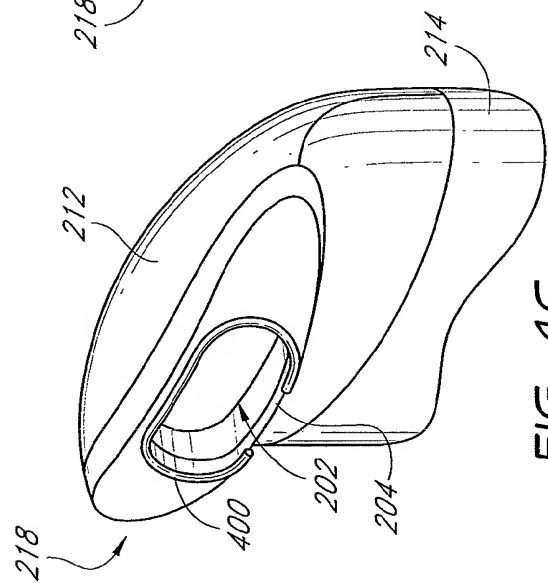
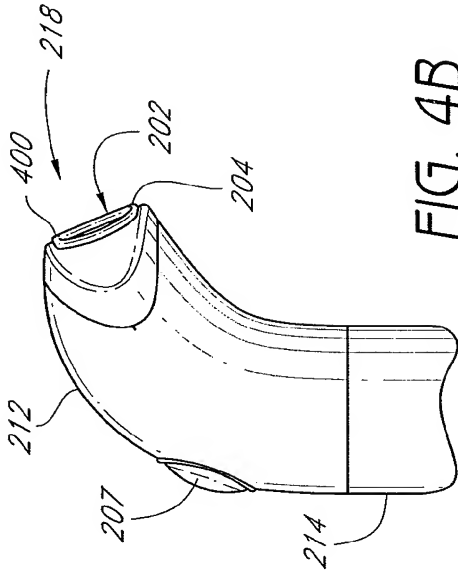
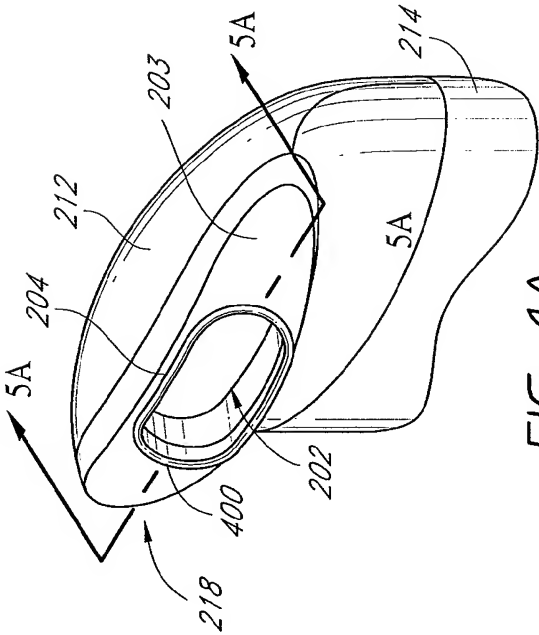


FIG. 5A

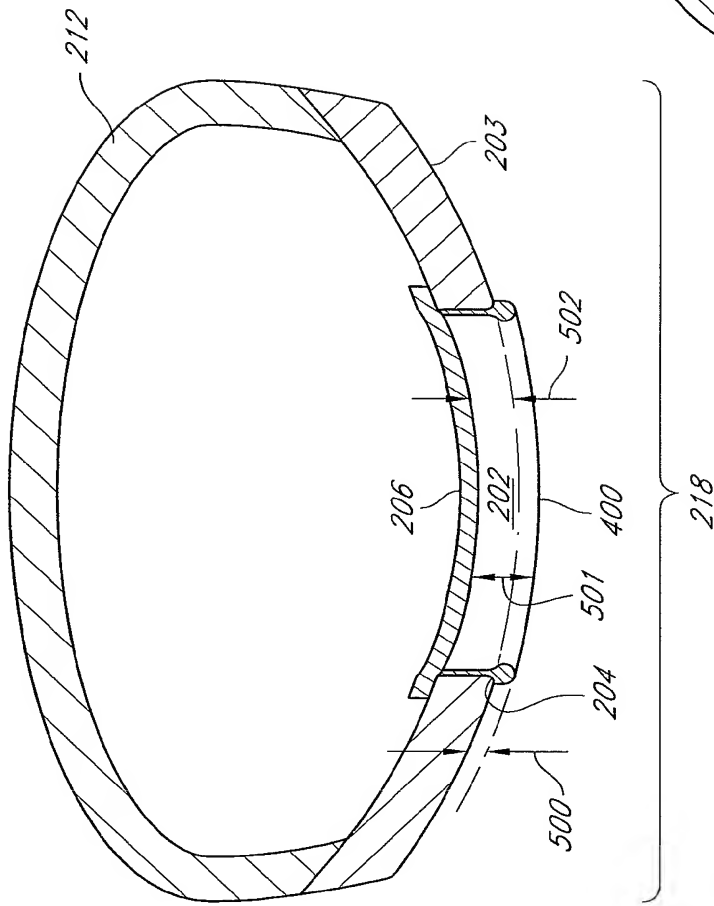
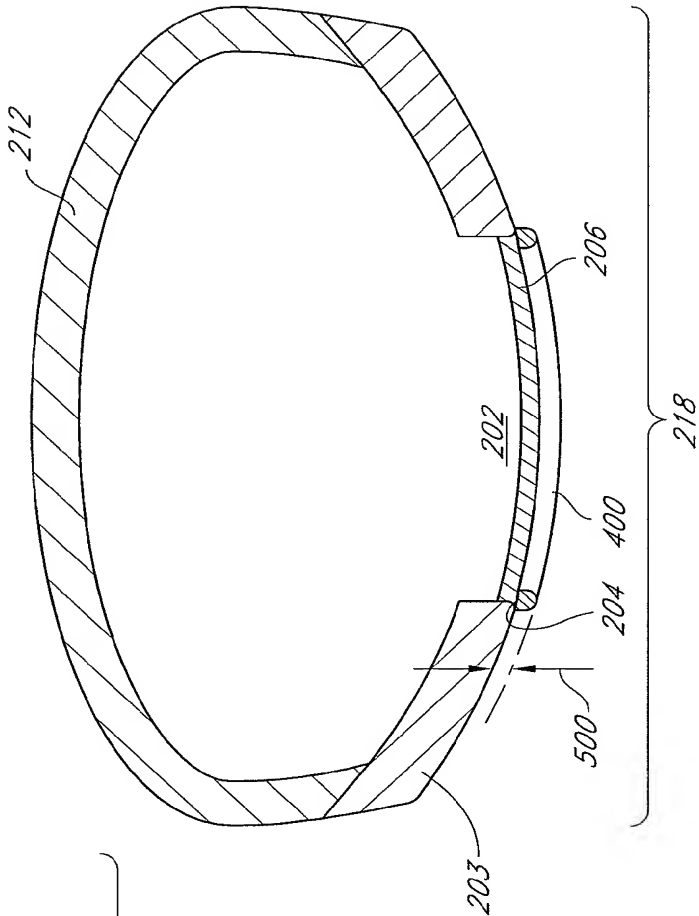


FIG. 5B



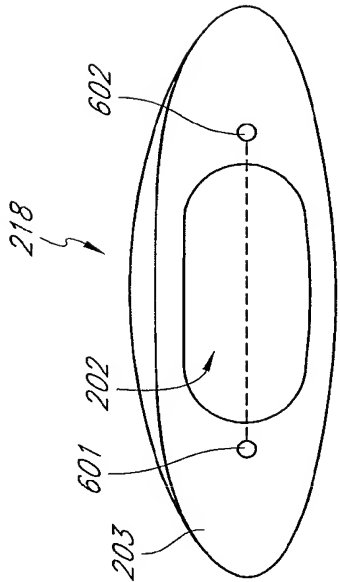


FIG. 6A

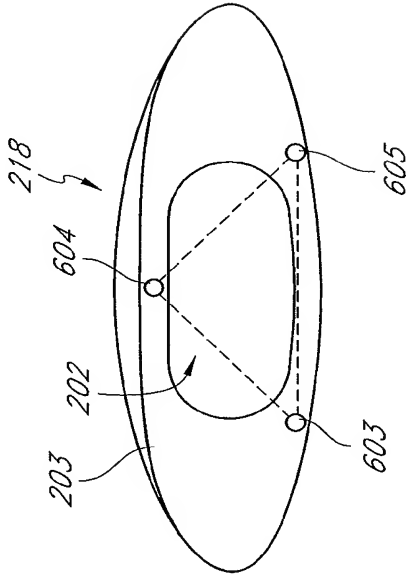


FIG. 6B

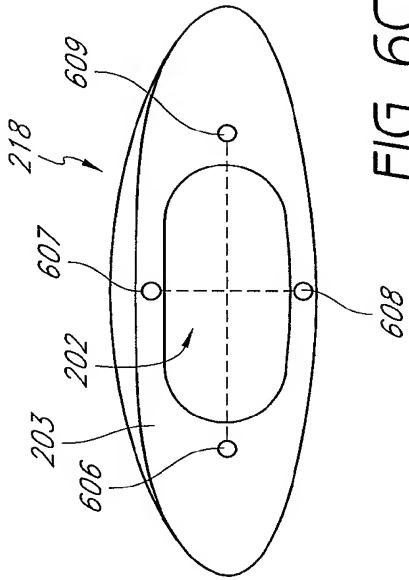


FIG. 6C

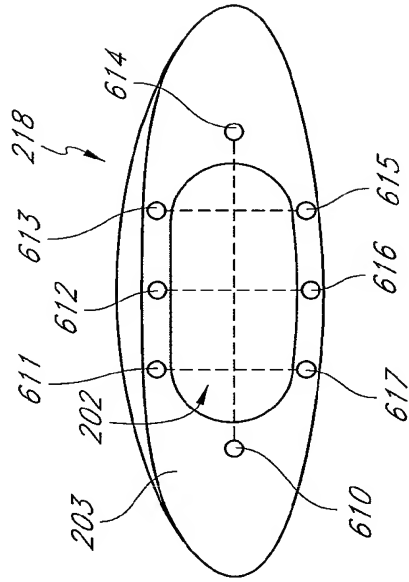


FIG. 6D

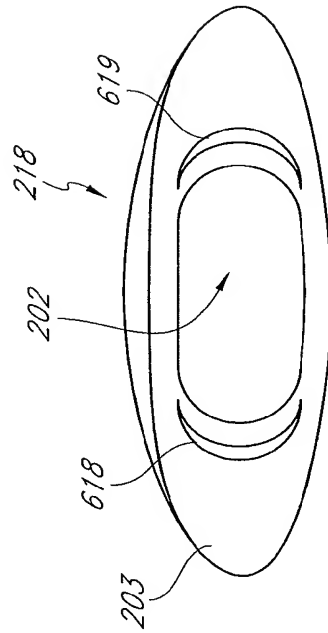


FIG. 6E

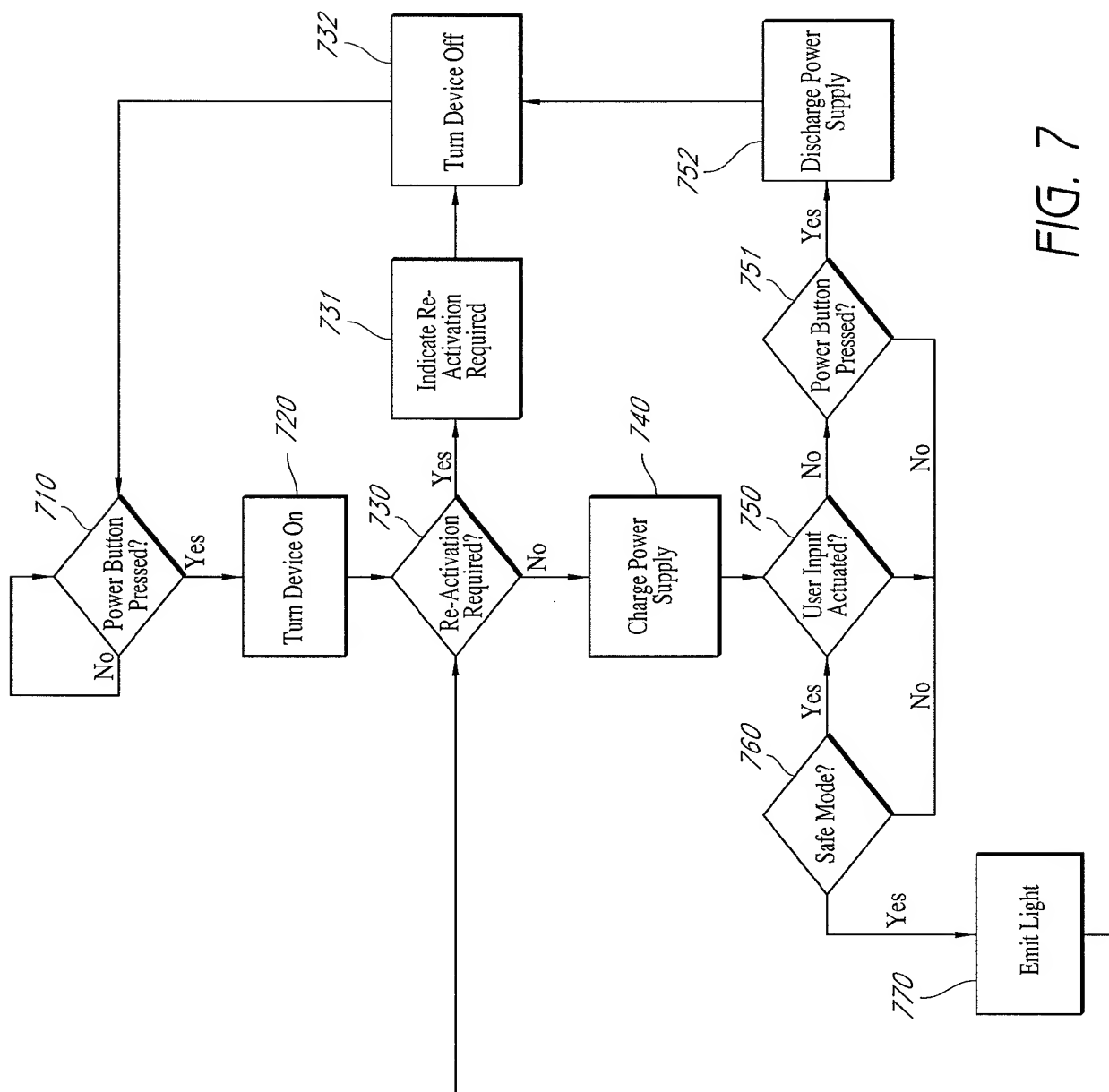


FIG. 7

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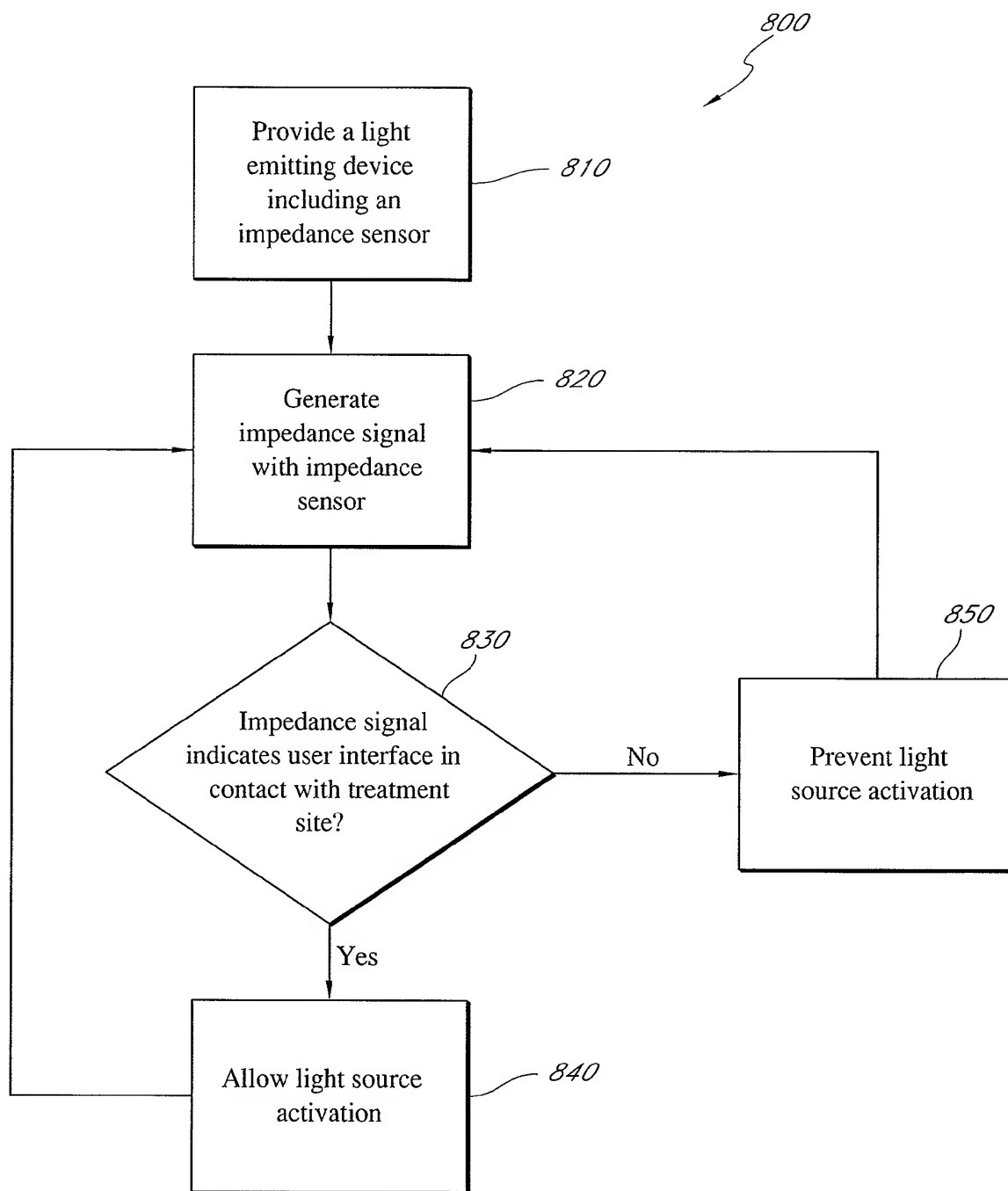


FIG. 8

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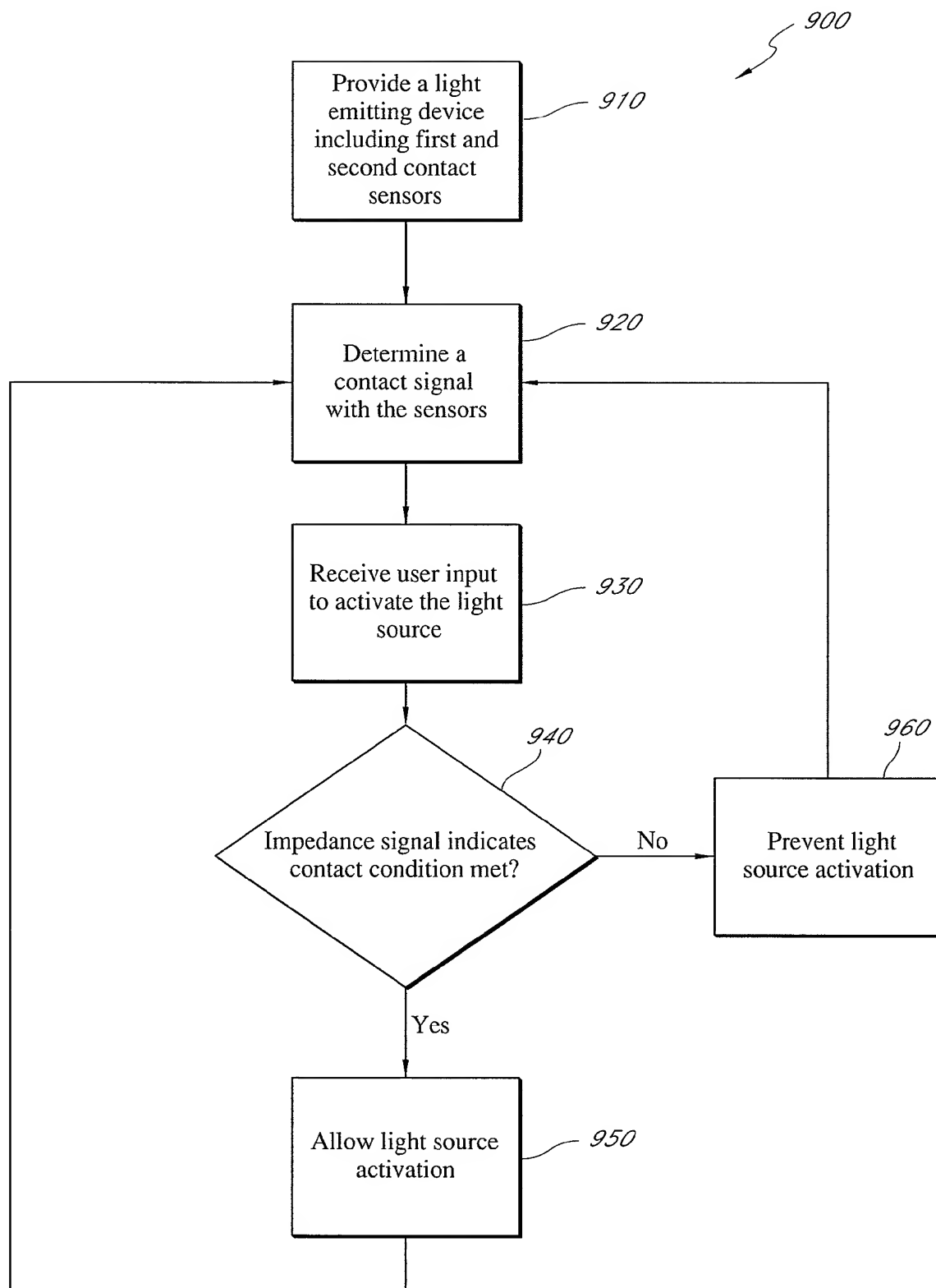


FIG. 9

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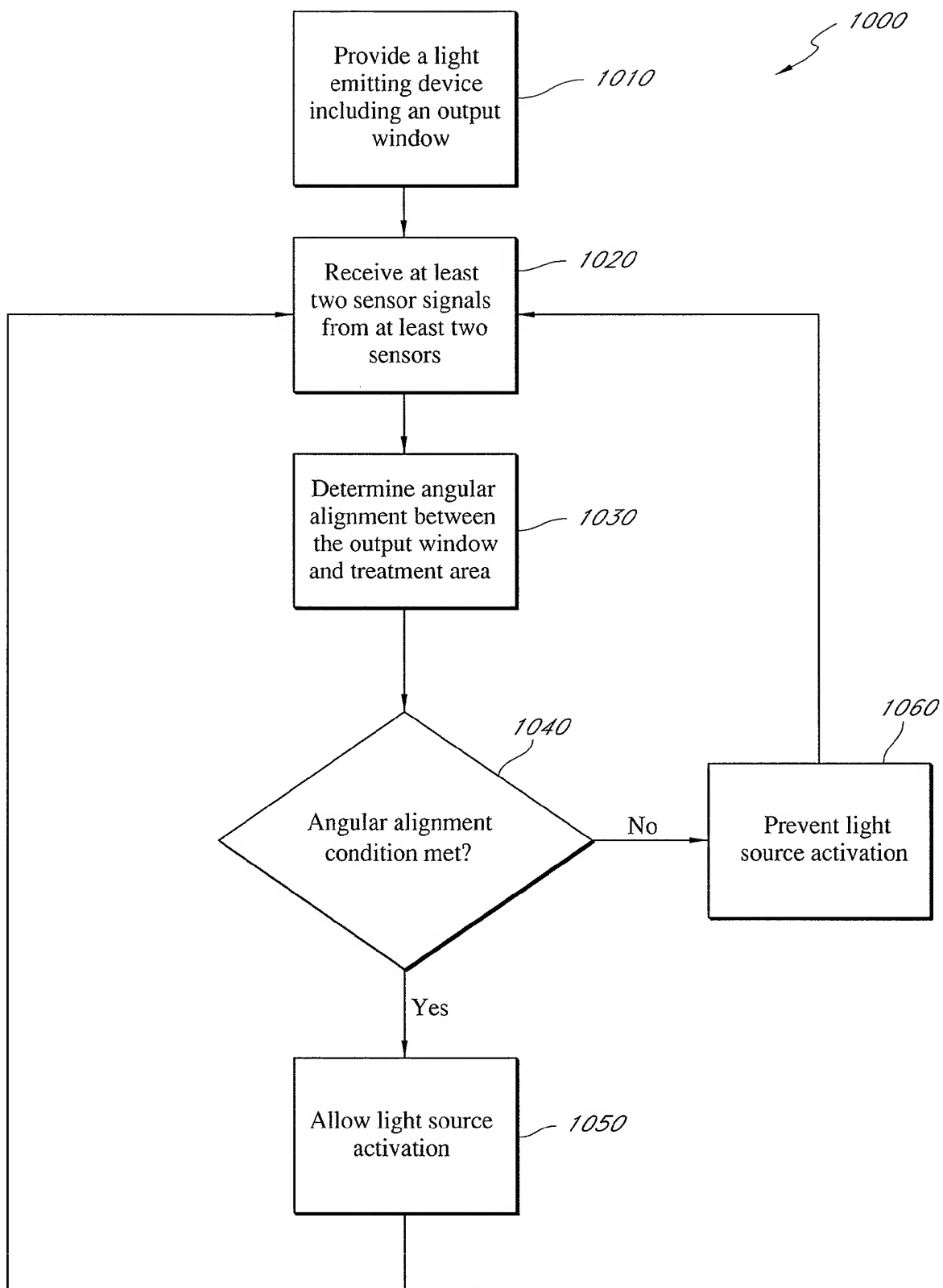
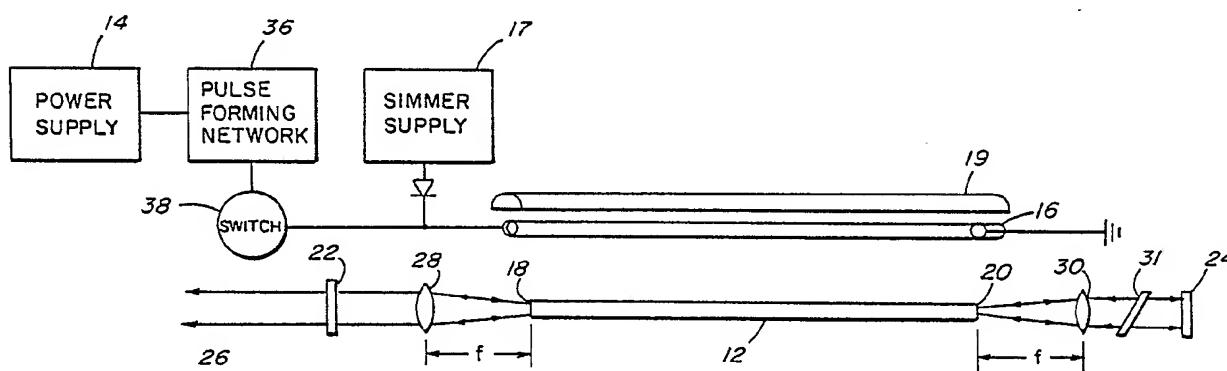


FIG. 10



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US85/02084</p> <p>(22) International Filing Date: 24 October 1985 (24.10.85)</p> <p>(31) Priority Application Number: 664,525</p> <p>(32) Priority Date: 25 October 1984 (25.10.84)</p> <p>(33) Priority Country: US</p> <p>(71) Applicant: CANDELA CORPORATION [US/US]; 19 Strathmore Road, Natick, MA 01760 (US).</p> <p>(72) Inventor: FURUMOTO, Horace ; 14 Woodridge Road, Wellesley, MA 02181 (US).</p> <p>(74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith and Reynolds, Two Militia Drive, Lexington, MA 02173 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: LONG PULSE TUNABLE DYE LASER**(57) Abstract**

A tunable dye laser has been found particularly suited to selective photothermolysis. A longer pulse duration which makes the system suitable for a wider range of applications is obtained by modifying the laser to generate a spatially noncoherent beam. The optical system at each end of the laser cell (12), which may include a lens (28, 30) or spherical mirror (32, 34), refocuses the aperture (18, 20) of the dye cell near to itself so that substantially all light emanating from the dye cell is returned to the dye cell until the light passes through one of the optic systems as a noncoherent laser beam. A tunable intracavity element (31) tunes the laser across the gain curve of the dye solution. The pulse duration of the laser beam can be selected from a range of durations up to about one millisecond.

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DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali		
FR	France				

-1-

LONG PULSE TUNABLE DYE LASERDescriptionField of the Invention

05 This invention relates to lasers and in particular to laser systems suitable for medical applications such as selective photothermolysis.

Background

10 The use of lasers in selective photothermolysis has been reported by Greenwald et al., "Comparative Hystological Studies of the Tunable Dye (at 577 nm) Laser and Argon Laser: The Specific Vascular Effects of the Dye Laser", The Journal of Investigative Dermatology 77:305-310, 1981, and by Anderson and Parrish, "Selective Photothermolysis: Precise
15 Microsurgery by Selective Absorption of Pulse Radiation", Science 220:524-527, 1983. In this technique, targeted tissues are heated by laser light, the wave length of which is selected to be specifically absorbed by the targeted tissues. The
20 laser pulse duration is tailored to the size of the target. Tissues surrounding the targeted structures are spared.

25 The above studies highlight the need for selecting lasers which meet both the spectral requirements of a given application and pulse duration requirements. It is important that the laser be tunable to select the color of the source

-2-

to match some spectral property of the targeted tissue. The special spectral features of targets require specific wavelengths, but only require moderate linewidths (1-4 nm) to induce selective effects. Proper laser pulse duration is important to heat target tissue to denature the tissues without boiling or vaporization. The temperature limits are tight, from body temperature of 35 C to a temperature well below boiling point, about 70 C. Ordinary calorimetry states that temperature rise is proportional to energy and inversely proportional to target volume irrespective of the time it takes to deliver the energy. If thermal diffusivity is added there is a pulse duration criterion and the energy must be deposited quickly to minimize heat dissipation to surrounding tissue. However, selective photothermolysis heat must not be deposited too quickly so as to exceed the boiling point in the targeted zone.

The situation gets more complex if small absorbing chromophores such as hemoglobin in blood cells are used as absorbers to treat blood vessels which are an order of magnitude larger. The radiation must be added at low intensities so as not to vaporize the small cells, left on long enough to heat the blood vessels by thermal diffusion to the point of denaturation and then turned off before the surrounding tissue is damaged.

Some control in intensity is available by the adjustment of the spot size of the pulsed radiation

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source. A source capable of delivering more than a joule is necessary so that spot sizes do not become too tiny with a concomittant increase in treatment time.

05 The above studies have shown the dye laser to be particularly suited to selective photother-
molysis. Dye lasers are readily tunable to selected wave lengths by means of the choice of dye, wave-
length selective filters in the cavity and the like.
10 Further, dye lasers can provide high output energies and short pulse durations. Unfortunately, the typical dye laser pulse duration of only a few microseconds or less is too short for many applica-
tions using selective photothermolysis. Dye lasers
15 with nanosecond or shorter pulses are preferred for subcellular organelle targeting and microsecond or shorter pulses are preferred for cell targeting. However, dye lasers do not typically provide the millisecond pulses which are best for blood vessels
20 and other small structures.

 It is generally recognized that the quenching of a dye laser after microseconds may be due to the accumulation of dye molecules in the triplet state by means of intersystem crossing from the singlet
25 state. Laser action in a dye laser starts from the singlet states. Molecules which cross over to the triplet state often absorb at the laser wavelength and inhibit laser action. The triplet state effect has been investigated and triplet state quenchers
30 have been reported for specific dyes. However,

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triplet quenchers for all dyes used in lasers have not been identified. But, even with the use of triplet quenchers, pulse durations of several hundred microseconds have only been obtained at low energy outputs of not more than a few tenths of a joule.

A second problem that makes it difficult to generate long pulses in a dye laser is the distortion of the liquid amplifying medium by absorbed, conducted and convected heat from the laser excitation source. Such distortions are unavoidable but must be minimized for laser action to continue for milliseconds.

Disclosure of the Invention

A laser has been developed which is more suitable for selective photothermolysis because the laser pulse duration is adjustable to durations approaching one millisecond. The present laser is based on the recognition that thermal distortion in the laser medium results in changes in the index of refraction in the medium and loss of resonating modes for which the laser is designed.

In accordance with principles of the invention, a multiple pass light amplifier, which may be considered a spatially noncoherent laser, comprises a cell having a medium excitable to an energy level with net optical gain and having apertures at opposite ends of the cell. The Fresnel number of the cell is greater than one, distinguishing it from

-5-

05 wave guide lasers. Means such as a flashlamp is provided for raising the medium to an inverted energy configuration. An optical system at each end of the cell images each aperture upon itself. As a result, substantially all light emanating from the aperture, within a wavelength band determined by the dye solution and any tuning element, is returned to the cell through the aperture. The optical system at one end of the cell allows part of the light to escape and be used.

10 The resultant beam of light which passes through one of the optical systems has directional concentration to a solid angle substantially less than one steradian, in the order of 10^{-4} steradian, although that concentration is somewhat less than 15 the solid angle of 10^{-8} steradian of conventional lasers. A pulse length greater than 100 micro-seconds, even approaching one millisecond, is possible even with output powers of over one tenth 20 joule. In fact, a pulse duration of 500 micro-seconds has been obtained with output powers in the order of joules.

25 In one form of the embodiment, the means for imaging the aperture on itself is a spherical mirror located a distance from the aperture about equal to its radius of curvature. In another embodiment, a lens is positioned between the aperture and the flat mirror. The lens is positioned at about its focal length from the aperture. The light emanating from 30 the cell is collected by the optical system and

-6-

reflected back into the cell. The light traverses the cell in a number of total internal reflections off other cell walls. The dye solution in an excited state amplifies the light rays traversing the cell. The gain medium has a continually changing index of refraction, light rays traversing the cell have no fixed pattern and resonator modes are not established; rather, the spontaneous emission localized in a cone determined by the reimaging optics is amplified on successive round trips through the cell throughout the duration of the laser pulse.

In a system designed specifically for selective photothermolysis, the power supplied to the flashlamp is provided with a variable pulse length circuit which provides for variable length pulses in the range of at least about 10 to 500 microseconds. Preferably, the system allows for pulses of up to one millisecond duration. An output of at least about one joule is provided.

Description of the Drawings

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily

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to scale, emphasis instead being placed on illustrating the principles of the invention.

Fig. 1 is an illustration of a preferred embodiment of the invention.

05 Fig. 2 is an illustration of an alternative embodiment of the invention using spherical mirrors.

Fig. 3 graphically illustrates a typical laser pulse plotted over the flashlamp excitation pulse and showing thermal distortion in the laser pulse.

10 Fig. 4 is a graphical illustration of a laser pulse over the flashlamp excitation pulse in a system embodying the present invention.

Fig. 5 is yet another embodiment of the invention having a bent gain medium.

15 Description of Preferred Embodiments

The earliest work in generating long pulses with dye laser concentrated on reducing triplet absorption effects. Dissolved oxygen and other chemicals considered to be triplet quenchers were added to the dye solution to deactivate any triplet states generated by long excitation pulses. Our present studies show that the additives or triplet quenchers do help to increase pulse duration. However, the additives may also help increase pulse duration because they lower laser threshold levels rather than minimize triplet absorption.

25 The early termination of laser action during a long excitation pulse is considered to be primarily of thermal origin. Heat is absorbed by

-8-

the solution and heat is convected from the lamp to the dye cell if the pulse is long enough. Acoustic velocities are in the order of 0.5 mm/microsecond, and with a dye cell bore of 4 or 5 mm there will be density and index of refraction gradients throughout the cell when laser pulses are longer than ten microseconds. If the gradients are very large, the result is a loss of identifiable resonating modes and quenching of the laser output.

A laser system embodying the present invention is shown in Fig. 1. The system is a modification of a conventional flashlamp excited dye laser. In such lasers, a laser medium in the form of a dye carried by a liquid is directed through the dye cell from one end to the other. Through external temperature control equipment, the medium is maintained at a uniform and constant temperature. To excite the laser medium, a high voltage developed in a power supply 14 is applied across a flashlamp 16. As in conventional flashlamp excited dye lasers, a small simmering current may be applied from a supply 17 to the flashlamp prior to starting a pulse from the supply 14 in order to develop a significant level of ionization in the flashlamp prior to discharge.

Light energy from the flashlamp is directed inward to the laser medium by means of a reflector 19. The energy from the flashlamp is absorbed by the laser medium and moves molecules in the medium from the ground state to excited singlet states. As in conventional lasers, as those molecules return to

-9-

their ground state they emit photons of a particular wavelength. Part of the light emanates from apertures 18 and 20 at each end of the dye cell. The light is returned through the apertures into the cell by respective mirrors 22 and 24. The returned photons react with molecules of the laser medium in the excited singlet state to cause those molecules to return to the ground state and themselves emit photons of the particular frequency. The thus emitted photons are in phase with the photons striking the molecules and are directed in the same direction as the original photons.

In a conventional laser, the optics at each end of the dye cell 12 are designed such that the photons travelling back and forth between the two mirrors 22 and 24 follow specific paths such that the photons resonate in particular modes. The photons resonate at a common frequency and phase. Finally, the light between the mirrors reaches an intensity such that a measurable amount passes through the mirror 22, which is not a full reflector, as a beam 26. In a conventional laser, the beam 26 is coherent and the divergence of that beam is very small, in the order of 10^{-8} steradians. To provide the resonating modes of a conventional laser, the laser optics must be precisely designed. Thermal distortions in the laser medium result in gradients in the index of refraction of the medium

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which in turn destroy the precise optic specifications of the system. The result is a loss of resonating modes and quenching of the laser output.

05 In the system of Fig. 1, lenses 28 and 30 are provided between respective apertures 18, 20 and mirrors 22, 24. In accordance with the present invention, the optics at each end of the dye cell are designed to return substantially all of the light emanating from the apertures 18 and 20 back
10 into the dye cell rather than to return just the spatially coherent light which travels substantially coaxially in the system. There is no attempt to establish resonating and coherent modes in the present system.

15 The lenses 28 and 30 are positioned at about their focal lengths f from the apertures 18 and 20. As a result, each aperture is reimaged onto itself through the lenses and flat mirrors. By thus selecting and positioning the lenses, substantially
20 all of the light emanating from the apertures, independent of resonating modes, is returned to the dye cell.

The optics mix the resonating rays and thoroughly homogenize the beams. Any thermal distortions which are induced by the flashlamp are of
25 little consequence because there are no resonator modes. The rays traverse the cell and are amplified but do not follow a precise path determined by the optics. Those rays that are highly deviated as to
30 miss the dye cell are lost. The homogenization is

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random and there is no phase relation at the wave front. The modes if any are randomly oriented and completely homogenized. The randomness is spatial as well as temporal. Spatial coherence is not
05 preserved but monochromaticity can be partially preserved with suitable wavelength selective elements. The medium has gain and a definite threshold and therefore is classified a laser.

As in conventional lasers, a tuning element 31
10 may be provided to tune the laser output within the gain curve of the dye solution. The tuning element can reduce the bandwidth of the beam to less than .01 nanometers and is used to match the absorption band of the target to enhance the desired physio-
15 logical effects. The most effective tuning elements are those that do not depend on this spatial coherence. The tuning element may be an etalon, a birefringent filter or a prism.

Fig. 2 illustrates an alternative embodiment of
20 the invention in which the optics at each end of the dye cell are replaced with spherical mirrors 32 and 34. Each mirror is positioned at a distance from the aperture 18, 20 which about equals its radius of curvature R. Each spherical mirror reimages the
25 aperture back on itself as do the optical systems in the prior embodiment.

The systems of Figs. 1 and 2 do not provide the coherent radiation of a conventional laser, and
their output beams diverge across a solid angle of
30 10^{-4} steradians. However, in an application such as

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selective photothermolysis, the large depth of field obtained from coherent radiation is not required. The concentration of light, though not as great as with the conventional laser, is significantly greater than the one steradian obtainable with nonlaser radiation and is adequate for selective photothermolysis. The advantage of the present system, as applied to selective photothermolysis, is that the beam is not limited by thermal distortion to a pulse duration of less than ten microseconds. Rather, pulse durations approaching one millisecond are possible.

There is a relation between laser pulse duration and the aspect ratio l/d where l is the cell length and d is the bore. A 12" gain length with a 4 mm bore cell lases for 125 microseconds before beam break up occurs. An 18" gain length laser with a 4 mm bore using the same set of optics lases for over 400 microseconds. The larger aspect ratio a/l where a is the radius of the dye cell bore and l the length of the cell, the longer are the pulses. The pumping intensities are kept constant by controlling the current density through the flashlamp. Energy levels up to five joules have been measured.

With the longer pulse durations available with the present system, the dye cell is now suited to a wider range of applications. Further, the pulse duration can be made variable to meet a number of different applications. To that end, a pulse forming network 36 is provided to generate electrical

-13-

pulses and transmit the pulses to the flashlamp 16, through a relay switch 38. The pulse width may be selected from the range of 10 microseconds to 500 microseconds and preferably to as high as one millisecond.

Standard plane-plane or confocal laser resonators show thermal effects at times in the order of ten microseconds. The symptom for thermal distortion is an instability in the amplitude of the laser output pulse. In general, flashlamp excitation pulses have a smooth envelope and the laser output pulse closely follows the excitation pulse. If thermal effects distort the laser medium, then the laser intensity will show an amplitude fluctuation. Figure 3 shows the output of a laser with a standard laser configuration; the laser pulse shows amplitude fluctuations after ten microseconds. Such amplitude fluctuations are seen in all long pulse dye lasers that use standard laser resonators. Figure 4 shows the same laser with a laser resonator configuration according to this invention that compensates for the thermal effects; the amplitude fluctuations are eliminated.

This system is similar to a waveguide resonator in that the sum of the focal lengths is less than 1, the optical length between the mirrors. However, it is not a waveguide resonator for the following reasons. (1) There is no restriction on the Fresnel number of the guide. The Fresnel number is equal to a^2 / l where a is the radius of the dye cell, l is the

-14-

wavelength, and l is the length of the cell. The waveguide resonator works with guides that have a Fresnel number less than one. Typical Fresnel number for the long pulse dye laser is 6 to 10 or even larger. For example, for a typical system a equals 2 mm, l equals 0.5 to 0.5 meters and equals .5 micrometers. (2) The waveguide laser has resonator optics that match the free space TEM_{00} mode to some of the lower order waveguide modes such as the HE_{01} or HE_{11} mode. There is no such restriction in the present system. There is no unique curvature for the mirrors to go with the aperture of the waveguide as in the true waveguide laser. (3) Resonating modes are absent in the present system, and any ray that is reimaged on the exit/entrance aperture can have net gain. The beam divergence is large but still less than that emanating from a guide with a given numerical aperture, or from a tube whose optical beam divergence is defined by the aspect ratio of the tube. Because of the large beam divergence, tuning elements that depend on minimum beam divergence are not effective as line narrowing elements. However, etalons are effective and linewidths to .03 Angstroms have been obtained using the present system. Birefringent filters have also been used to tune the present system.

The present laser advantageously satisfies the criteria for selective photothermolysis. A dye laser emitting at 575 nm with pulse durations up to

-15-

400 microseconds has been developed for the treatment of cutaneous vascular lesions such as birthmarks. Such birthmarks are caused by a high density of blood vessels close to the surface of the skin. These blood vessels can be eliminated by selective photothermolysis. The selective photothermolysis laser should emit at 575 nm where blood has secondary absorption maxima at least an order of magnitude larger than that of pigmented tissue of fair skin. The laser should emit pulses about one millisecond long to couple energy into the blood vessels which are several hundred microns in diameter. The vessel will then be heated to denaturation temperature without vaporizing the blood cells. The laser should then be turned off before tissue surrounding the blood vessels is damaged.

A laser with variable pulse duration can be used in selective photothermolysis for a number of medical treatments other than the treatment of cutaneous vascular lesions. These include hemostasis of bleeding ulcers, suppression of choroidal neovascularization that leads to blindness, and hemostasis after the removal of eschar in burn therapy. If exogenous chromophores can be selectively injected into target tissue, the principle of selective photothermolysis treatment with tunable, variable pulse duration lasers can be extended to cover many medical applications too numerous to mention.

Fig. 5 illustrates a modification of the system of Fig. 1 which is possible with the present system.

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Because the primary parameter of importance is the relation between the focal length of the optical system and the distance to the dye cell aperture and not the length of the dye cell itself, a bend as shown in the dye cell 36 of Fig. 5 is possible. With a conventional laser, that bend would provide different path lengths through the medium which would destroy the resonating modes of the system.

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

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CLAIMS

1. A multiple pass light amplifier comprising:

a cell having a medium excitable to an energy level with net optical gain and apertures at opposite ends thereof, the Fresnel number of the cell and optics being greater than one;

means for raising the energy level of the medium to have net optical gain; and

an optical system at each end of the cell for imaging each aperture near to itself .

2. A multiple pass light amplifier as claimed in Claim 1 wherein each optical system comprises a spherical mirror positioned at a distance from the aperture about equal to its radius of curvature.

3. A multiple pass light amplifier as claimed in Claim 1 wherein at least one of the optical systems comprises a flat mirror and a lens positioned between the mirror and the aperture at about the focal length of the lens from the aperture.

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4. A method of amplifying light to develop a pulsed beam of light at least 100 microseconds in duration and at least one tenth joule comprising:

05 for at least 100 microseconds,
 energizing a medium in a cell to an
 energy level in which the medium
 has net optical gain; and

15 from each end of the cell
 collecting substantially all light
 within a wavelength band emanating
 from the cell and returning the
 light into the cell such that the
20 cell amplifies the light to form a
 spatially noncoherent beam of light
 of directional concentration to a
 solid angle substantially less than
 one steradian.

- 25 5. A method as claimed in Claim 4 wherein the
 spatially noncoherent beam of light has a
 directional concentration to a solid angle of
 about 10^{-4} steradian or less.

- 30 6. A method as claimed in Claim 4 wherein the
 bandwidth of the amplified beam is reduced by
 means of a tuning element.

7. A system for generating a beam of light for selective photothermolysis comprising:

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a pulsed tunable dye laser for
amplifying light to generate a
spatially noncoherent beam of light
with an energy level of at least
about one joule and a pulse dura-
tion greater than 10 microseconds;
and

a pulse forming circuit for
generating variable electric pulses
for energizing the tunable dye
laser, the pulse forming circuit
providing variable length pulses
through the range of at least about
10 microseconds to 500 micro-
seconds.

8. The system of Claim 7 wherein the pulse forming
circuit generates pulses of about one milli-
second duration.

9. The system of Claim 7 wherein the pulsed
tunable dye laser comprises:

a cell having a dye solution
excitable to an energy level with
net optical gain and apertures at
opposite ends thereof, the Fresnel
number of the cell being greater
than one;

means for raising the medium
to the excited energy level; and

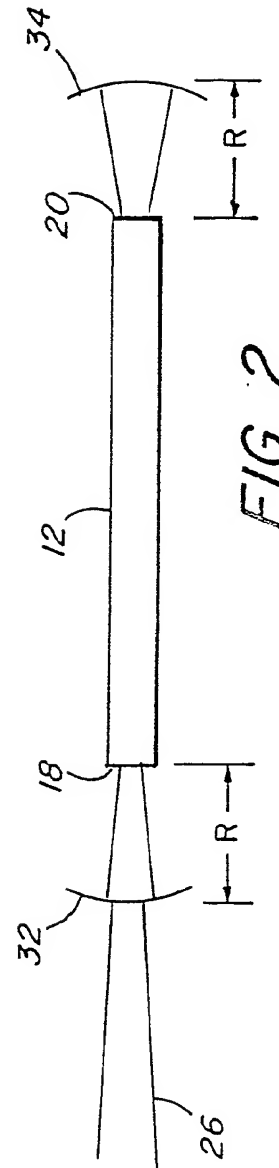
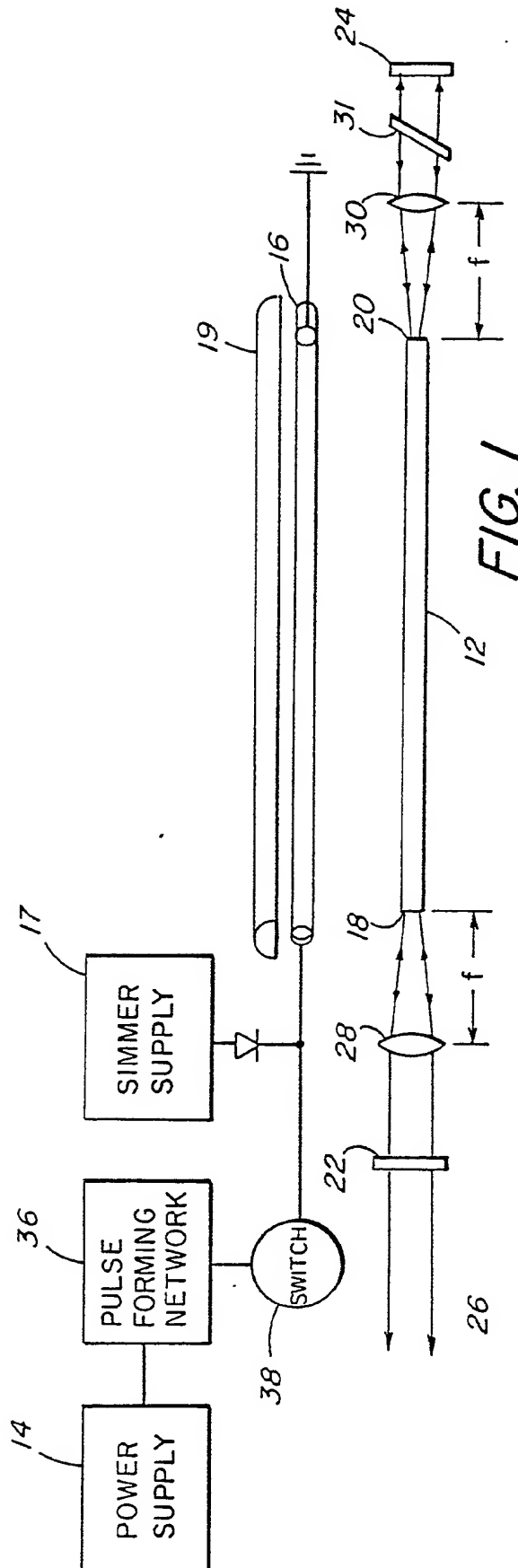
-20-

an optical system at each end
of the cell for imaging each
aperture near to itself such that
substantially all light within a
wavelength band emanating from the
aperture is returned to the cell
through the aperture until the
light passes through one of the
optical systems as a beam.

05

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10. The system of Claim 9 further comprising a tuning element to tune the laser across the gain curve of the dye solution.



2/2

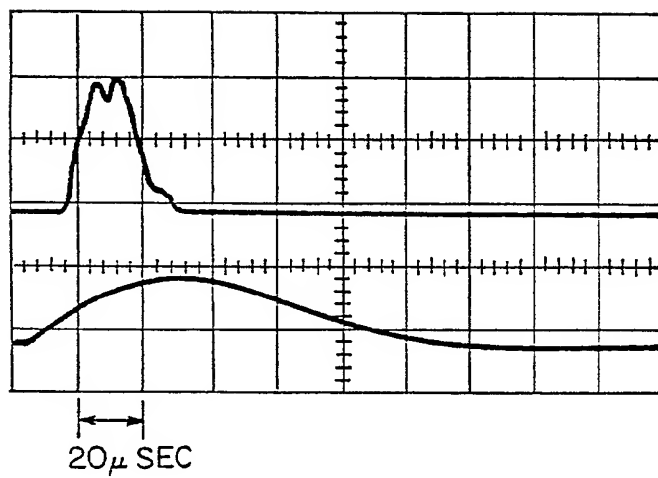


FIG. 3

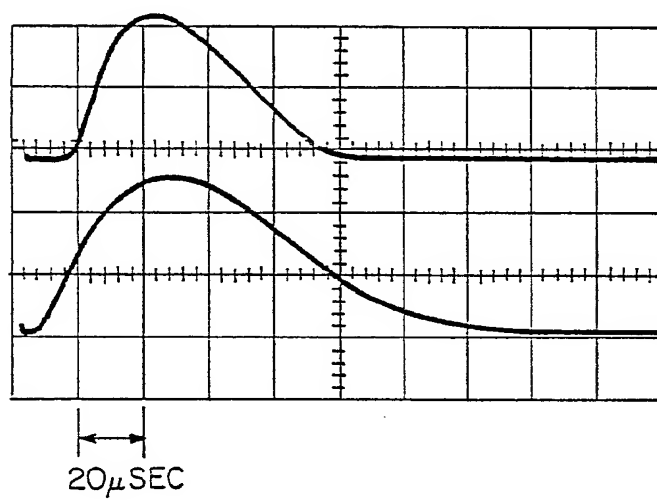


FIG. 4

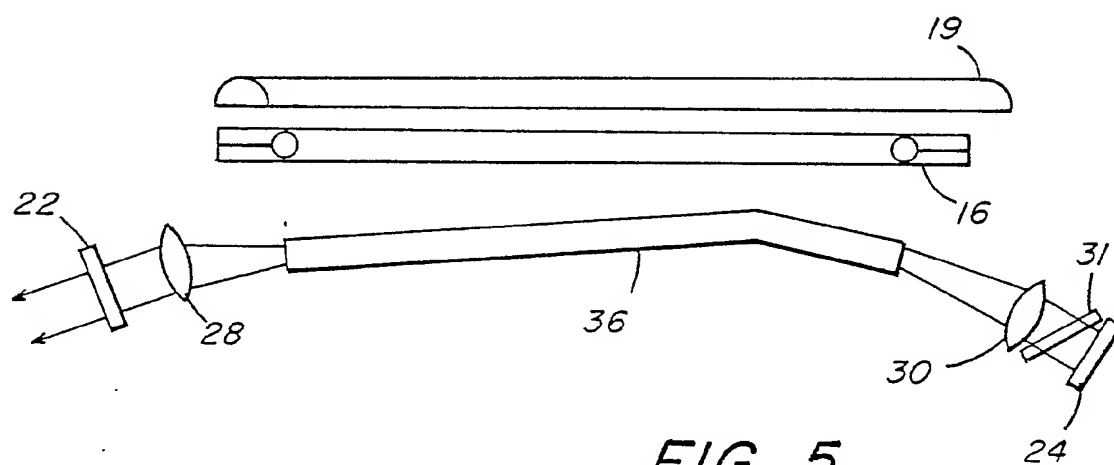


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 85/02084

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC: IPC ⁴ : H 01 S 3/08; 3/106; 3/692; A 61 B 17/36		
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched †</div> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">Classification System †</div> <div style="width: 70%;">Classification Symbols</div> </div> <div style="margin-top: 10px;"> IPC⁴ H 01 S 3/08; 3/106; 3/092; 3/20 </div> <div style="text-align: center; font-size: small; margin-top: 10px;"> Documentation Searched other than Minimum Documentation to the extent that such Documents are Included in the Fields Searched ‡ </div>		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, † with indication, where appropriate, of the relevant passages ‡	Relevant to Claim No. ‡
A	IEEE Journal of Quantum Electronics, vol. QE-10, no. 10, October 1974 (New York, US) E.A. Maunders et al.: "Experiments on improved unstable mode profiles by aperture shaping", pages 821-822, see particularly figure 1 and page 821, right-hand column, paragraph 2	1
A	Optics and Spectroscopy, vol. 49, no. 5, November 1980 (New York, US) V.S. Smirnov: "Methods for reducing the divergence of lamp-excited rhodamine 6G solution lasers", pages 526-529, see particularly page 526, right-hand column - page 527, end of left-hand column	1-3,5
A	Applied Optics, vol. 21, no. 15, August 1982 (New York, US) J. Jethwa et al.: "High-efficiency high-energy flashlamp-pumped dye laser", pages 2778-2779, see figures 2,5-6	4,7 ./.
<div style="font-size: x-small;"> * Special categories of cited documents: † "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu- ments, such combination being obvious to a person skilled in the art "Z" document member of the same patent family </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
5th February 1986		28 FEB. 1986
International Searching Authority EUROPEAN PATENT OFFICE		Signature of Authorized Officer M. VAN MOL

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	Applied Optics, volume 18, no. 8, April 1979, New York, (US) T.K. Yee et al.: "Simmer-enhanced flashlamp-pumped dye laser", pages 1131-1132, see figure 1; page 1131, right-hand column, last two lines --	4,7
A	IEEE Journal of Quantum Electronics, volume QE-10, no. 8, August 1974, New York, (US) G. Holtom et al.: "Design of a Birefringent filter for high-power dye lasers", pages 577-579, see page 578, right-hand column, lines 7-8 --	6,10
A	US, A, 3426293 (ELIAS SNITZER) 4 February 1969, see claim 1 -----	1,6,10

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

- see Annexe

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210 (supplemental sheet (2))

Multiple inventions as follows:

- claims 1-3 : A multiple pass light amplifier comprising a cell with apertures and an optical system for imaging each aperture near to itself
- claims 4-6 : A method of amplifying light to develop a pulsed beam with a particular duration, energy and directional concentration
- claims 7-10 : A system for generating a beam of light for selective photothermolysis comprising a tunable dye laser with a particular excitation arrangement

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/US 85/02084 (SA 11203)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/02/86

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

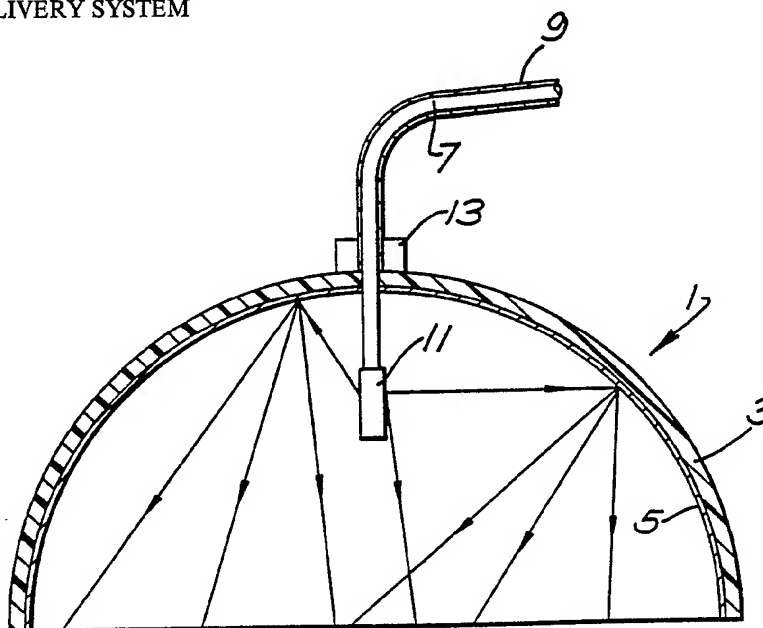
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3426293	04/02/69	None	

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB89/00796 (22) International Filing Date: 13 July 1989 (13.07.89) (30) Priority data: 8816648.3 13 July 1988 (13.07.88) GB (71)(72) Applicants and Inventors: ROWLAND, Adrian, Charles [GB/GB]; 13 Mary Ann Gardens, London SE8 3DP (GB). ALLARDICE, James, Todd [GB/GB]; 10 Gainsborough Square, Bexleyheath, Kent DA6 8BU (GB). (74) Agents: WILLIAMS, Trevor, John et al.; J.A. Kemp & Co., 14 South Square, Gray's Inn, London WC1R 5EU (GB).		(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: LIGHT DELIVERY SYSTEM**(57) Abstract**

A device for uniformly irradiating an area of a surface which accurately defines the area under irradiation and collects lights reflected from the area and scatters it back towards the surface. The device comprises a hemispherical shell (3) whose inside surface is coated with a diffuse reflector and a light source (11) mounted in the shell. The light source may be a diffusing device connected to a laser remote from the shell (3) via an optical fibre (7). In use the shell (3) is placed against the surface under illumination so that the edges of the shell (3) define the area under illumination and the use of the diffusely reflecting surface of the shell prevents any escape of light. A deformable sheet of partly reflective and partly transmissive material may be placed across the open mouth of the hemisphere to cover the target area to increase the uniformity of illumination when the device is used on uneven surfaces. The device is particularly useful in photodynamic therapy.

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LIGHT DELIVERY SYSTEM

This invention relates to an apparatus and method for illuminating an area of an object and in particular to a device in which the total amount of luminant energy delivered to the area can be accurately determined. It is particularly applicable to medical treatment techniques which rely on the illumination of body tissue in order to achieve desired effects e.g. photodynamic therapy and bio-stimulation.

It has been found that certain types of cancer including skin cancer and breast cancer can be treated successfully using a technique known as photodynamic therapy or PDT. In this technique a photosensitizing agent, usually haematoporphyrin derivative (HpD) is administered to the patient and this agent concentrates in the cancerous tissue. It is thought that the agent concentrates in the tumour because it leaks out of the vasculature in the tumour into the surrounding tumour tissue. The lymphatic system within the tumour is not as efficient at removing the HpD as is the lymphatic system in the rest of the body and so for a certain time period there is proportionately more HpD in the tumour than in the rest of the body. At some point in that time period the area of the body with the tumour is irradiated with laser light having wavelength of about 630

nm from an argon dye laser. The effect of the laser light on the HpD is to cause oxygen radicals to be released which destroy the surrounding tumour tissue. In the case of breast cancer the illumination stage of the treatment is usually given twenty-four to seventy-two hours after administration of the HpD agent, though with skin cancer, laser treatment can be delivered up to three or four weeks after the administration of the HpD.

Conventionally the treatment area has been illuminated using laser light directed down an optical fibre, the tip of the fibre being moved over the treatment area. One problem with this method is that the illumination consists of an intense centre spot with the intensity falling away gradually from the centre of the spot. This means that it is difficult to give an even dosage of light to a large area. Furthermore, it is very easy to apply too much light to some areas. In order to attempt to alleviate this problem it has been proposed to deliver the light using an optical fibre bundle with micro-lenses on the end of each fibre or diffusers in the light path to give a broader, more even, illumination area. Another proposal is to control the intensity profile of the beam emerging from an optical fibre by interposing an oblique glass plate between the laser and the optical fibre.

A further problem, which also occurs with the

improved techniques mentioned above, is, however, that since the surface of the body being illuminated is to some extent reflective, it is difficult to determine exactly how much light is absorbed to act on the HpD. The reflectivity of different parts of the treatment area may vary and so even dosage estimates based on an estimated or measured reflectivity are not particularly good. A typical dosage estimate with one of the techniques above was that 30-400 J/cm² was delivered to the patient. It can be seen that the upper limit of the range is over ten times the lower limit and this is unsatisfactory both from the point of view of that treatment and for statistically processing the results from many treatments to try to improve the technique.

It has also been proposed to use laser light in other medical treatments, e.g. bio-stimulation in which tissue is irradiated with low power laser light. It has been suggested that this irradiation has certain beneficial effects and has been used to speed-up the healing of wounds, as a beauty treatment and in physiotherapy. Laser illumination has also been used in the treatment of vascular abnormalities such as port wine stain and the removal of tattoos. Other types of light have also been used, for instance, infra red or ultra violet for treating various conditions e.g. the treatment of skin disorders e.g. psoriasis. In some of these agents which render the skin

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sensitive to the particular light being used have been administered to the patient. However, similar problems with achieving a uniform illumination and calculating the amount of light delivered to the surface have been found.

The present invention provides a device to deliver a defined quantity of light to a surface comprising a light source for illuminating the surface and means for scattering light reflected from the surface so that it can be directed back onto the surface. Preferably the scattering means are adapted to provide a substantially uniform illumination of the surface.

In more detail the present invention provides apparatus for illuminating an area of an object, comprising a delivery device including a light source for illuminating the area and a concave diffusely reflecting surface, wherein the diffuse reflecting surface is adapted to define the area to be illuminated when the device is held in contact with the object and to collect light reflected from the surface of the object and scatter it back towards the area.

Preferably the light source, which conveniently is the tip of an optical fibre, is arranged to illuminate the diffusely reflective surface so that light from the light source is reflected towards the treatment area. This can be achieved by diffusing the light with, for example, a ceramic reflector or possibly a p.t.f.e. or etched diffuser on the

optical fibre.

The present invention also provides a method of illuminating an area of an object comprising the steps of:

illuminating the area of the object with light from a light source illuminating a concave diffusely reflective surface maintained confronting the area,

positioning the diffusely reflecting surface with its edges in contact with the object so that it collects light reflected from the surface of the object and scatters it back towards the area and so that the edges of the concave diffusely reflecting surface define the area being illuminated.

The light used may be laser light as in the conventional PDT techniques or may be non-coherent light for some applications. The diffusely reflective surface may be the inner, concave surface of a part-spherical, e.g. hemispherical, shell-like structure with the optical fibre and diffusing device attached in its top. In use, the shell is held with its edges in contact with the object under illumination so that any light reflected off the illuminated area is collected and scattered back thereto by the diffusely reflective surface. A reflectivity of 99% can be achieved by coating the concave surface with reflective paint, or any suitable highly reflective coating, e.g. a ceramic.

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If the area to be illuminated is smaller than the base area of the hemisphere then parts of the area which do not require illumination can be masked with a highly reflective surface. This means that light striking the reflective surface is not lost but is reflected back towards the diffusely reflective surface and eventually onto the area to be illuminated.

It will be appreciated that with the present invention the amount of light delivered to the treatment area can be accurately determined since none of the light delivered to the area is allowed to escape. This is because almost all of the light reflected from the illuminated area is scattered back towards it by the diffuse reflective surface and since the reflective surface is held in contact with the object, no light can escape under the edges. Furthermore, the use of a diffusing device on the end of the optical fibre delivering the laser light and the use of the diffusely reflective surface mean that the intensity of the illumination is substantially uniform over the whole of the treatment area.

The invention also has benefits for the safety of the operator and, if it is being used in medical treatment, for the patient, as once the reflective surface is in contact with the body the laser system is closed and there is very little risk of accidental injury to the operator or

to the patient caused by escaping laser light. It is possible to arrange for the laser or other light source only to be switched on when the reflective surface is placed in contact with the body - e.g. by a pressure sensitive or temperature sensitive switch or by some other switching means.

If desired the target to be illuminated may be treated with an agent to absorb the light. e.g. a photodegradable or photocensitizing agent. For example where the invention is to be used in photodynamic therapy, e.g. for the treatment of cancer, then a suitable agent which might be preferentially absorbed by certain cells e.g. cancerous cells, e.g. HpD can be administered to the patient some hours before the laser treatment. An accurate amount of light can then be delivered to the treatment area and this allows the operator to calculate more accurately what depth of tissue may be destroyed. This not only allows better treatment of an individual patient but also allows a better correlation of results to treatment conditions and so the best conditions for the treatment of the cancer and different types of cancer may be determined more easily.

The invention is also useful for the treatment of port wine stains, homeopathic processes and bio-stimulation where the fact that the illumination is uniform and defined allow better control of the treatment process.

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The invention has been described above in relation to use in medical treatment, e.g. for photodynamic therapy. It is, however, useful in any process where it is desirable to uniformly illuminate an area and to avoid losing light by reflection from that area. Thus the device could be used in industrial processes for manufacture e.g. for curing substances e.g. plastic resin composites or for optical processes in the manufacture of electronic devices e.g. microchips. In such processes the fact that no light escapes and that a well defined area is illuminated mean that the process can be run economically. Clearly for such processes types of electromagnetic radiation other than optical laser light might be appropriate.

The device may also be useful for promoting biological growth of animals or particularly plants, where again the fact that the illumination is accurately defined and no radiation is allowed to escape can improve the efficiency and economy of the process.

The shape of the reflective surface is not thought to be particularly critical, the preferred embodiment in this specification uses a hemisphere but other concave shapes can be used.

The size of shell is chosen to be close to the size of the area to be illuminated.

A typical size of shell used for medical purposes

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would be a few inches in diameter, but larger or smaller shells, e.g. large enough to cover the complete pelvic area, may also be used where appropriate. It is also possible for the reflective surface to be formed on a flexible member so that it can be shaped to match the shape of the area to be treated. These allow the operator to avoid treating areas which do not need treatment.

As an alternative to using a diffusing device on the end of the optical fibre, the fibre may be mounted to direct light onto a diffuse reflector, made from, e.g. a reflective ceramic, mounted in front of the diffusely reflective surface to reflect the light back onto it.

The apparatus may further comprise a deformable sheet of material across the open end of the concave surface, e.g. a sheet of white rubber or synthetic rubber, and which has a high reflectivity, appreciable transmission and low-absorption. The absorption should be low enough to prevent undesirable light loss, e.g. about 1%, and the transmission high enough to allow sufficient illumination of the target surface. For medical applications about 9% is acceptable. The reflectivity should be, for such applications, about 90%.

The invention will be further described by way of non-limitative example with reference to the accompanying drawings which:-

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Figure 1 is a cross-sectional view of one embodiment of the invention;

Figure 2 is a partially cutaway view of the embodiment of Fig 1 in use;

Figure 3 is a schematic view of a second embodiment of the invention in use;

Figure 4 shows a third embodiment of the present invention: and

Figure 5 shows a fourth embodiment of the invention

As can be seen by Fig 1 the apparatus comprises a light delivery device 1 which consists of a hemispherical relatively rigid, plastics shell 3 whose inside, concave surface is coated with a reflective coating 5. The coating is a reflective paint or ceramic which provides a diffuse reflective surface. It is possible to achieve a reflectivity as high as 99% or more with such a coating. The shell, intended for medical use in PDT is about 5-15cm in diameter and about 1-2mm thick.

Laser light is supplied to the device along an optical fibre 7, which may be a single fibre or a bundle of fibres. In this embodiment the fibres are teflon coated and retained within a p.t.f.e. sheath 9. The fibres terminate at a diffusing element 11, which is in this embodiment a p.t.f.e. cylinder or, alternatively, a ceramic or etched fibre diffuser (formed by exposure to hydrofluoric acid)

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mounted in the hemispherical shell. The fibre is connected to the shell by a two-part block 13 having a bore down the centre through which the fibre and sheath pass. The fibre is trapped in an interference fit between the two parts of the block 13. In the illustrated embodiment the diffuser 11 is positioned about 2cm below the top of the shell. Light transmitted down the fibre passes into the diffuser 11 and is emitted from the end of the diffuser in a number of directions. Some light will be transmitted directly to the treatment surface, but some light will also be transmitted towards the diffusely reflective surface 5. Various light paths are shown in the diagram. Light striking the diffusely reflective surface will be scattered therefrom, partly towards the treatment area and part towards opposing regions of the reflector. It will be appreciated, therefore, that a fairly uniform illumination is achieved within the region defined by the edges of the reflective shell.

Although not shown in the diagram, the shell may be provided with a sensor and switch so that the laser supplying light to the optical fibre 9 is only switched on when the shell is pressed into contact with the surface which is to be illuminated. This results in less chance of the patient or operator being accidentally exposed to laser light and thus improves the safety of the apparatus.

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In Fig. 2 the device is shown schematically in use on part of a patient 15. This shows the device used in a situation where the area 17 which is to be illuminated is smaller than the base area of the reflector. The parts of skin which would undesirably be exposed to the light have therefore been masked using a reflective tape 19, for example, aluminium tape. This means that light supplied to the delivery device 1 which misses the exposed treatment area and hits the tape is reflected back up to the diffusely reflective surface and scattered back towards the treatment area.

Figure 3 shows a second embodiment of the invention in use. In this embodiment the reflective shell 22 is formed from a flexible plastics material so that it may be deformed to cover a desired treatment area more accurately. A further feature of this embodiment, which can also be used in the other embodiments of the invention, is that light is supplied to the device by several optical fibres 27 each connected to a diffusing device 11 and spaced over the surface of the shell. This enables a greater amount of light to be delivered per unit time if necessary and helps in maintaining a substantially uniform light distribution particularly in the case where the shell is deformed.

The above embodiments have been described as being supplied with laser light by an optical fibre. However, the

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invention is also usable in other applications in which e.g. ultra violet or infra red light or any electromagnetic wave radiation are used. In such applications the light may be delivered to the delivery device using a light guide e.g. liquid or fibre light guide or other types of radiation guides or the light source may be mounted in or on the shell.

Figure 4 shows schematically a third embodiment of the invention in which light delivered to the device by an optical fibre 9 is directed onto a reflector 30 in this case spherical, though other shapes may be used, which reflects light back upon to the diffusely reflective surface which, in turn, scatters it onto the treatment area. The reflector 30, which may be a highly reflective ceramic, is mounted on the shell 1 by a mounting 32.

Figure 5 shows diagrammatically a fourth embodiment of the invention which uses a reflector 1 and light delivery system 9 and 30 as in the previous embodiments, but also includes a deformable partly reflective partly transmissive sheet 50 across the open end of the reflector which, in use, covers the target area. The sheet 50 may be a sheet of white rubber or synthetic rubber and has a high reflectance preferably greater than 17% and more preferably still greater than 77% , very low absorption preferably less than 5% and appreciable transmission. Typical values which have

been effective in practice are, for instance, 90% reflection, 9% transmission and 1% absorption. This sheet 50 is particularly useful when the device is used to illuminate an uneven surface as it conforms or partly conforms to that surface and improves the uniformity of the light delivered to the target.

With the invention it is possible to calculate the amount of light supplied to the treatment area much more accurately than with the prior art devices. This is because substantially all of the light supplied to the device is eventually absorbed by the treatment surface. None is allowed to escape - because the reflector shell is placed in contact with the object being illuminated and any light reflected from the treatment surface is eventually scattered back by the diffuse reflector towards the treatment surface. Furthermore, the fact, that virtually none of the light supplied to the device is allowed to escape means that the device is particularly safe to use.

While the invention has been described in relation to the medical treatments, as discussed above it is applicable wherever it is required to deliver an accurate and uniform irradiation to a surface, or to substantially reduce the amount of light lost from a system, or to define the area to which radiation should be delivered. The effect of this device in minimizing losses has benefits in that for

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a given total energy absorption requirement for a given power output of the radiation source, less time will be needed to bring about that effect.

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CLAIMS

1. Apparatus to deliver a defined quantity of light to a surface comprising a light source for illuminating the surface and means for scattering light reflected from the surface so that it can be directed back onto the surface.

2. Apparatus according to claim 1 wherein the scattering means are adapted to provide a substantially uniform illumination of the surface.

3. Apparatus for illuminating an area of an object, comprising a delivery device including a light source for illuminating the area and a concave diffusely reflecting surface, wherein the diffusely reflective surface is adapted to define the area to be illuminated when the device is held in contact with the object and to collect light reflected from the surface of the object and scatter it back towards the area.

4. Apparatus according to claim 3 wherein the light source is adapted to illuminate the diffusely reflective surface so that light from the light source is scattered towards the area of the object.

5. Apparatus according to claim 3 or 4 wherein the light source is a source of laser light.

6. Apparatus according to claim 3,4 or 5 wherein

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the light source includes an element for distributing the light onto the reflecting surface.

7. Apparatus according to claim 6 wherein the element is a diffusely reflecting body

8. Apparatus according to claim 6 wherein the element is a p.t.f.e. cylinder.

9. Apparatus according to any one of the preceding claims wherein the diffusely reflective surface is the concave surface of a shell-like structure, the edges of the shell defining the area to be illuminated when it is held in contact with the object.

10. Apparatus according to claim 9 wherein the concave surface is coated with a reflective ceramic to form the diffusely reflective surface.

11. Apparatus according to any one of the claims 3 to 10 further comprising a deformable sheet of material across the open-end of the concave surface, said material having a high light reflectance, appreciable light transmission and low light absorption for the light from said light source.

12. A method of illuminating an area of an object comprising the steps of:

illuminating the area of the object with light from a light source preferably a laser light source, illuminating a concave diffusely reflective surface maintained

confronting the area,

and positioning the diffusely reflecting surface with its edges in contact with the object so that it collects light reflected from the surface of the object and scatters it back towards the area and so that the edges of the concave diffusely reflecting surface define the area being illuminated.

13. A method according to claim 12 wherein the diffusely reflecting surface is illuminated by light delivered by an optical fibre to a diffuser, e.g. of ceramic or a p.t.f.e. cylinder,

14. A method according to claim 12 or 13 wherein the area is provided of with a degradable agent for absorbing the light.

15. A method according to claim 12,13 or 14, wherein light from the concave surface is transmitted through a deformable sheet covering the surface, the sheet having properties of high light reflectance, appreciable light transmission and low light absorption.

FIG. 1

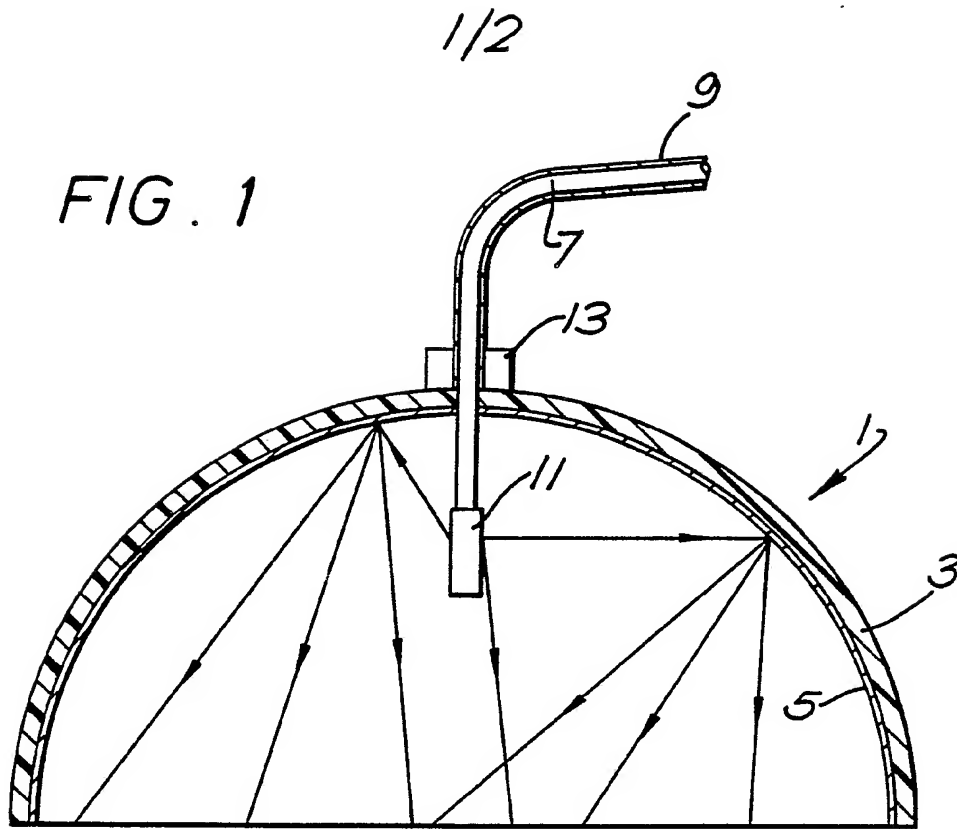
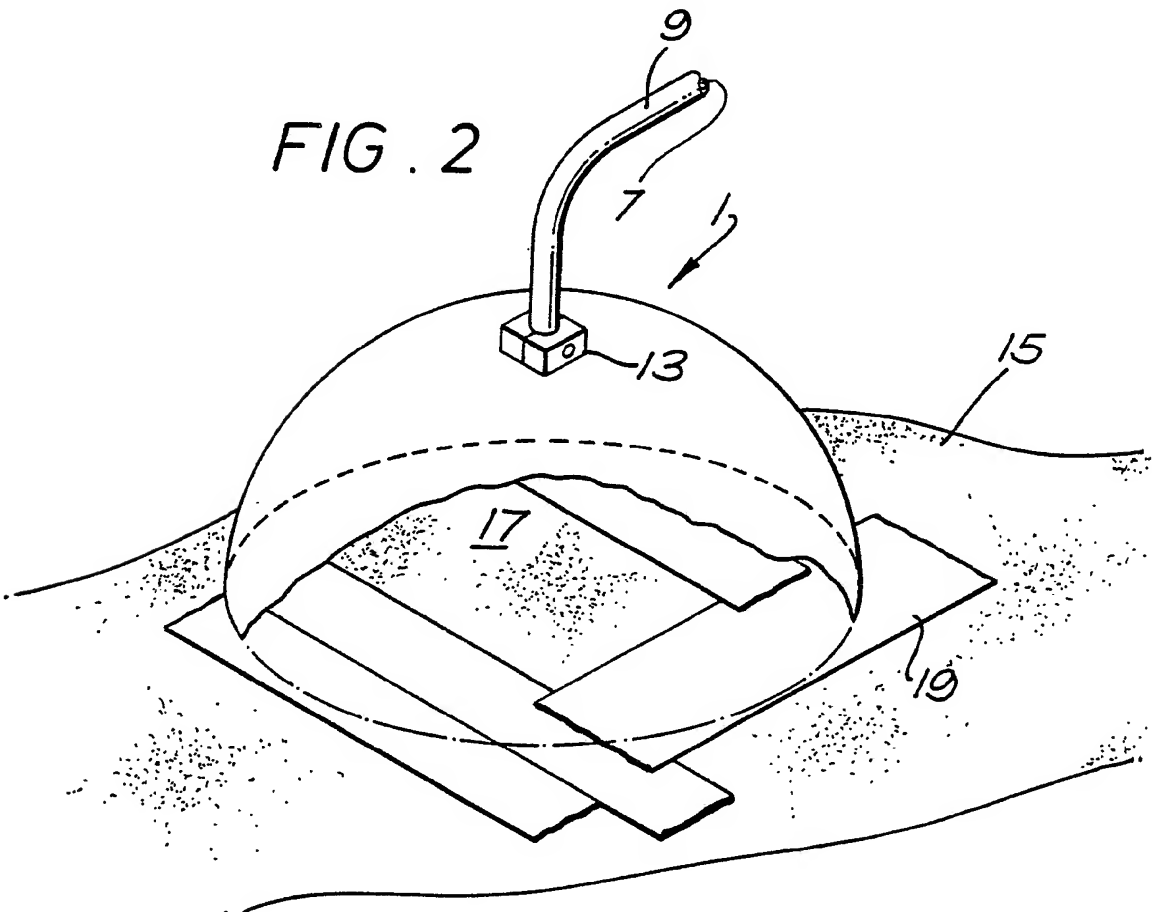


FIG. 2



SUBSTITUTE SHEET

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FIG. 3

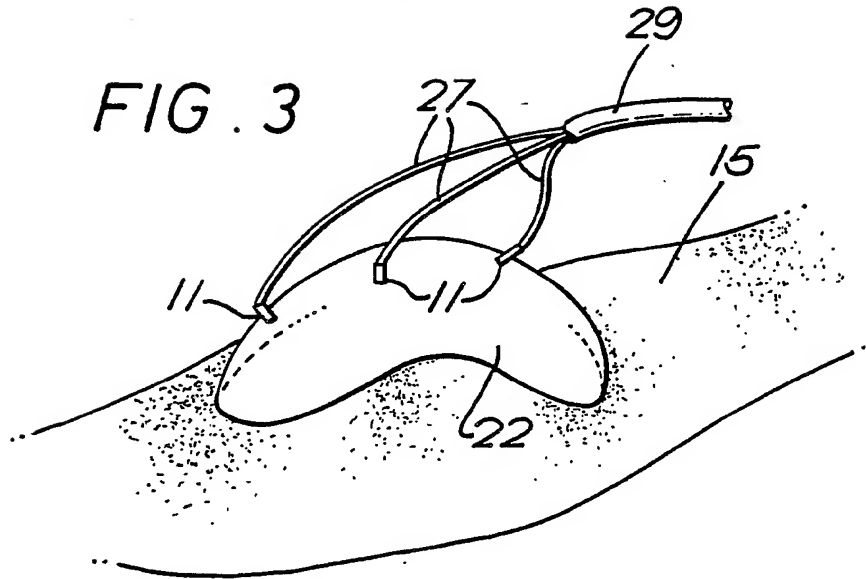


FIG. 4

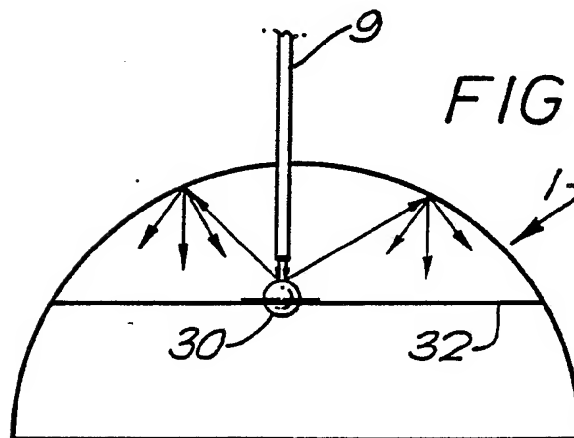
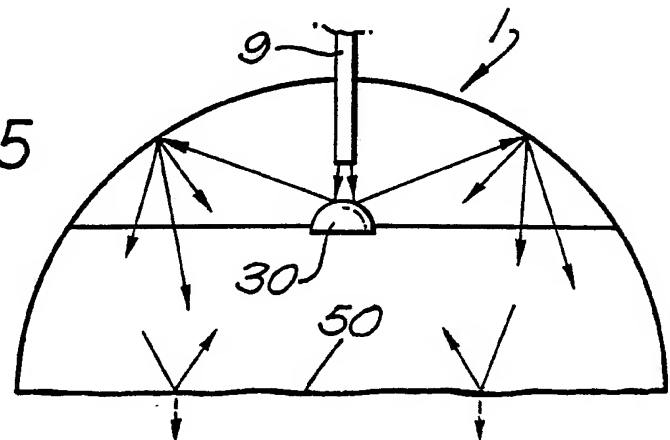


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00796

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 N 5/06		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁵	A 61 N, A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	FR, A, 2591902 (COLLIN) 26 June 1987, see page 3, lines 28-32; page 6, lines 7-11; figure 4 --	1-5,9,12
X	DE, A, 3300517 (MERSMANN) 26 July 1984, see page 9, lines 12-20; page 52, lines 32-37; page 99, lines 9-33; figures 93-96 -----	1-10,12
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search <div style="text-align: center; font-weight: bold;">18th October 1989</div>	Date of Mailing of this International Search Report <div style="text-align: center; font-weight: bold; font-size: 1.2em;">13 NOV 1989</div>	
International Searching Authority <div style="text-align: center; font-weight: bold;">EUROPEAN PATENT OFFICE</div>	Signature of Authorized Officer <div style="text-align: right; font-weight: bold; font-size: 1.2em;">T.K. WILLIS</div>	

ANNEX TO THE INTERNATIONAL SEARCH REPORT
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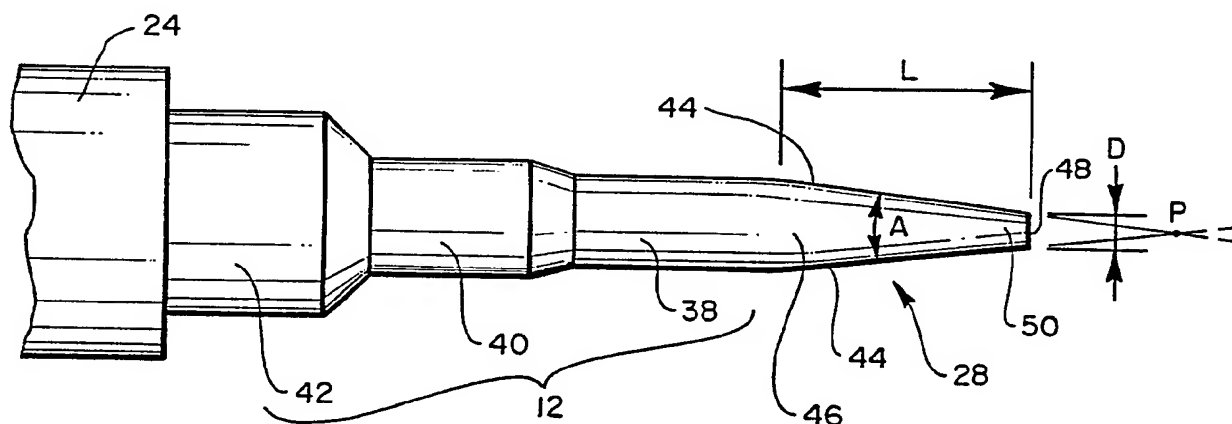
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2591902	26-06-87	None	
DE-A- 3300517	26-07-84	None	



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(54) Title: INTEGRAL END STRUCTURE FOR MEDICAL LASER WAVEGUIDE**(57) Abstract**

End structures for a medical laser fiber (38) integrally formed from a molten portion of the fiber (38) have sides free from polishing abrasions. The end structure may assume a frustoconical shape (28, 60) with sides (44) tapering smoothly from the fiber (38) to a flat surface (48) normal the axis of the fiber (38). Alternatively, a spherical (184) portion having a diameter (E_1) greater than the fiber (38) is disposed concentrically with the fiber (38). The end structure may include a bend portion (132, 152, 162, 202) diverting therefrom at a bend angle (B, B_1, B_2, B_3), being radially coextensive with the end of the fiber (38), and ending in a tip that assumes a spherical shape (208) or a frustoconical shape (134, 154, 164) that tapers to a flat surface (142) normal the plane of the bend portion (132) and parallel the fiber (38). An alternate tip embodiment has sides (104) that flare smoothly from the fiber (38) to a terminus (100) having a diameter (D_3) greater than the diameter of the fiber (38).

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INTEGRAL END STRUCTURE FOR MEDICAL LASER WAVEGUIDE

BACKGROUND

1. Field of the Invention

This invention relates to optical waveguides for medical use to transmit laser energy from a medical laser to tissue to be treated according to a medical procedure. More specifically, the present invention relates to a tip for focusing laser energy from the output end of an optical fiber core used in medical procedures, including those undertaken on the walls of passageways in the body.

2. Background Art

Laser energy has been used for some time in a variety of medical and surgical procedures to coagulate, vaporize, excise and anastomose selected body tissues. Lasers are now routinely used, not only to remove tissues in surgical procedures, but to induce hemostasis, to close blood vessels, ducts and other body passageways, and to destroy obstructions in body passageways. Such obstructions include, for example, fatty deposits, plaque, calcification, and embolic clots that develop in blood vessels.

The nature of each application determines the appropriate manner in which to configure and operate the laser delivery system. This includes the type of laser to

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employ, and the laser intensity and time exposure that should be used.

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For example, conventional argon lasers emit light in the blue and green wavelengths of 454.5 to 514.5 nanometers (nm). Energy at such wavelengths is readily absorbed by the hemoglobin found in red blood cells. Thus, argon lasers have been used to coagulate small vascular abnormalities, such as port wine strains, telangiectasias, spider veins, and diabetic retinopathy.

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On the other hand, dye pumped argon lasers, flash pumped dye lasers, double neodymium yttrium aluminum garnet (Nd:YAG) lasers, and copper vapor lasers emit yellow light having wavelengths in the 530 to 590 nm range. Light in these wavelengths is even more readily absorbed by hemoglobin than is the blue-green light of the conventional argon laser. Accordingly, the conventional argon laser has recently been displaced in coagulating small vascular abnormalities by lasers that emit yellow light.

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The light emitted by a primary neodymium yttrium aluminum garnet (Nd:YAG) laser is, on the other hand, only minimally absorbed by hemoglobin. Light from this laser tends to penetrate and scatter into tissue and shows little or no selectivity for coagulation of the blood vessels therein. Due to this property of the light of the primary Nd:YAG laser, it is used instead to coagulate large volumes

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of tissue. The primary Nd:YAG laser is now used to facilitate in vivo removal of tissue with minimal bleeding.

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Typically, the laser energy for use in such medical procedures is transmitted from the laser dictated by the application involved through an optical waveguide to the tissue to be treated. The waveguides most often take the form of a fiber core of optically transmissive material having an input end for receiving the laser energy and an output end remote therefrom for delivering the laser energy to the tissue. Hand-held probes are optically coupled at the output end of the optical waveguide. Initially, these probes were not designed to make contact with the tissue being treated.

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A disadvantage of this feature of laser energy transmission systems resided in an inability to efficiently deliver all of the energy in the waveguide to the precise tissue to be treated. The separation between the tissue and the output end of the optical waveguide encouraged the scattering of laser energy, as that energy was required to pass first through the optical interface between the probe and air and then through a second optical interface between the air and the tissue. In addition, this same separation resulted in a defused pattern of laser energy in or on that tissue, preventing the efficient and selective delivery of the laser energy to the precise tissue needing to be

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treated. This caused unwanted destruction in surrounding tissues.

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As a result, laser probes were developed which make direct contact with the tissue to be treated or, at a minimum with the layer or layers of tissue lying immediately thereover. Various focusing structures were utilized at the output end of the optical waveguides employed in these contact laser probes. The focusing structures directed the laser energy emerging from the waveguide in a pattern conducive to the medical procedure being undertaken.

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In United States Patent No. 4,273,127 the focusing structure takes the form of a scalpel-shaped optically transmissive body mounted at the output end of an optical fiber core so that laser energy delivered from the fiber will emerge from the light guide at the cutting edge thereof in a cone-shaped pattern. A surgeon is able to effect tissue incision both by applying pressure to the scalpel-shaped body, and by utilizing laser energy.

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In the laser probe disclosed in United States Patent No. 4,592,353 a lens and cover separate from an optical fiber core are interposed at the output end of the fiber core in order to produce a structure specifically designed for tissue coagulation. The contact probe disclosed in United States Patent No. 4,693,244 comprises an optical fiber core with a separate focusing structure in the form

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1 of an artificial sapphire with a tapered extremity. The
larger end of the sapphire is positioned opposite the
5 output end of the optical fiber core with an air gap
therebetween, permitting the tapered end of the sapphire to
contact tissue for surgical treatments, such as incision,
coagulation, and hemostasis. United States Patent No.
10 4,736,743 discloses a similar probe tip, distinct from the
optical fiber core of the delivery system, and made of a
natural or artificial ceramic material. In each reference,
15 the focusing structure at the output end of the optical
fiber core is a structure distinct from the fiber core
itself. This requires optical and physical coupling
between the two components of the system.

20 Contact probes having tips that require optical and
physical coupling to the output end of an optical fiber
core have numerous drawbacks. Due to the near physical
difficulty of exactly matching the flat faces of the
25 opposing faces of the sapphire and the fiber core, for all
practical intents an air gap results between the two
components. First, a substantial loss of laser energy
occurs as the laser energy from the optical fiber core
30 crosses into the air gap at the output end of the fiber
core and thereafter crosses from the air gap into the input
end of the focusing tip. This dissipation of laser energy,
expectable at an interface between materials of differing
35 refraction indexes, dissipates energy that could otherwise

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be delivered to the tissue to be treated. Moreover, it is a loss which manifests itself in a form of the generation of heat.

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Heat produced at the interface between the output end of an optical fiber core and a distinct focusing tip coupled thereto, has a number of adverse consequences. First, the resultant thermal stress accelerates aging of the probe tip and the optical fiber core. This contributes to rapid failure rates in the components of the probe, increasing the cost of its use and the downtime for its repair.

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In endoscopic applications, the waste heat generated at the interface between the output end of the optic fiber core and the separately formed focusing tip used therewith must be removed from the body of the patient. Failure to promptly and completely do so can cause damage in tissues surrounding the site, leading to complications and extended healing times. The mechanisms for effecting this cooling process require the introduction and removal of fluid or gas coolants into the body of the patient. These are not only costly systems, but being relatively complex, they are susceptible to regular breakdowns. Even a momentary malfunction risks unnecessary tissue damage, where the lasers being cooled thereby is not also promptly de-energized. Cooling systems also introduce into the surgical site alien materials, some of which have in recent

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1 years been suspected of causing fatalities due to embolisms
or other bodily reactions to the chemicals and heat
5 involved.

Focusing structures which are distinct from the
optical fiber core to which they are coupled are generally
manufactured from crystalline materials, such as sapphire,
10 diamond, and quartz. Unfortunately, the crystalline
structure of such materials places restrictions on the
shape of focusing tips that can be manufactured therefrom.
The sides of tips made of such crystalline materials cannot
15 be made to be smoothly tapering or smoothly flaring without
polishing. Doing so, however, creates fine polishing
abrasions on the surface of the tip corresponding to the
size of the polishing abrasive employed in the process.
20 The presence of polishing abrasions on the sides of a
crystalline tip for an optical waveguide causes part of the
laser energy reaching the tip to be diffused through those
sides. This impacts adversely the transmission efficiency
25 of the resulting probe. By scattering laser energy from
the sides of the focusing structure, rather than from the
tip thereof, undesirable coagulation is also caused in
30 tissue adjacent to but not precisely at the end of the tip.

The cost of growing, polishing, and installing
crystalline structures of the size required for the tip of
a laser fiber core is relatively high. When the focusing
35 structure on a laser probe is distinct from the optical

1 fiber core thereof, complicated means of mechanically
coupling these two components must be utilized. Such means
5 of coupling include press fittings, jewelry-style prongs,
and adhesives. These impact the cost of the resultant
structure, and each is afflicted with increased risk that
tip components loosen. This necessitates repair, or even
10 a search in the surgical site for a completely detached tip
component. These factors not only make the cost of
producing composite waveguides so high as to mandate their
sterilization and reuse, eliminating the possibility of
15 disposability.

Even where an attempt to avoid some of these problems
is made by fabricating a focusing structure that is
integral with the end of an optical fiber core, polishing
20 is used to shape that focusing structure. Accordingly
polishing abrasions are found on the sides of the tip, and
this degrades its internal reflectiveness.

25 It should also be noted that polishing abrasions
constitute surface flaws in such tips. As such the
polishing abrasions can start fractures that cause tip
failures, a correlation is possible between the presence of
30 such surface abrasions and a lack of structural solidity in
the probe tip on which they exist.

Particularly difficult surgical conditions exist in
relation to endoscopic procedures to be effected on the
35 walls of tubular passageways in the body, such as those of

1 the circulatory, digestive, urological and respiratory
systems. Typically the output end of the laser probe
5 utilized is advanced within the bodily passageway involved
to the site of the required surgery. Nevertheless, the tip
structure of known probes directs laser energy therefrom in
a direction that is parallel to the longitudinal axis of
10 the probe, which is also parallel to the bodily passageway
in which the probe is located.

It is most difficult, therefore, to direct laser
energy toward a surgical site that is on the immediate wall
15 of the passageway. Laser energy is instead directed along
the axis of that passageway, posing the risk of
inadvertently damaging the walls of the passageway at any
point ahead of the laser probe tip where the passageway
20 curves. To orient the tip of such laser probes laterally
toward the immediate wall of the passageway, it has been
necessary in the past to resort to auxiliary structures
which grasp the laser probe at the output end thereof and
25 bend it toward the desired surgical site. Such auxiliary
equipment by adding to the complexity and the size of the
probe involved increases cost, decreases reliability, and
30 limits the smallness of the bodily passageway in which such
surgical procedures can be effectively and safely
undertaken.

In some prior devices, the desired end has been
35 achieved by a composite structure involving a brass cap

1 with a lateral window therethrough which is placed over the
end of a bare optical fiber. Laser energy transmitted to
5 the end of the fiber is reflected internally until it
passes through the window to be focused on the tissue of a
tubular body passageway adjacent thereto. Naturally in
this process of internal reflection substantial heat is
10 generated in the metallic cap, posing a hazard to adjacent
tissue which is not targeted for treatment by laser
surgery.

15 As the capacity develops to deliver laser energy to a
surgical site while maintaining high transmission
efficiency, equipment refinements to meet specific of the
diverse needs of the laser surgeon can be expected. Some
20 surgical procedures will require the precision focusing of
laser energy in order, for example, to effect a cutting
function. By cutting, sections of tissue can be detached
and thereafter removed from the surgical site. On the
25 other hand, it may be desired that tissue removal can be
effected by direct vaporization. To do so will require
laser energy to be transmitted in a broad, intense beam
onto a large area of tissue. In certain endoscopic
30 applications, for example, it may be desirable to vaporize
tumorous tissue, removing the vapor from the body cavity,
rather than detaching the tumor and then cutting it into
small pieces that can be manipulated out of the surgical
35 site through a small opening thereinto. The desirability

1 of either of these options can arise when the surgical site
is located on the wall of a passageway immediately to the
5 side of the laser probe, rather than axially alignable with
the laser probe. Additionally, it has been discovered that
certain patterns of laser energy transmission are more
effective than others in producing hemostasis during laser
10 surgery. Accordingly, the need exists to develop surgical
laser contact tips capable of transmitting laser energy in
a variety of patterns and intensity.

15 An additional problem encountered in the area of laser
waveguides, such as those used in medical procedures,
arises because the splicing together of two or more optical
fiber cores requires for a satisfactory transmission
20 interface therebetween that the output end of one of the
fiber cores be smaller in diameter than the input end of
that to which it is to be optically coupled. Thus, each
optical fiber core in a sequence of fibers spliced together
25 to effect a lengthy transmission must be larger in diameter
than the preceding fiber core. Where an optical laser
fiber core becomes damaged, and the damage is to be
remedied by coupling a section in substitute therefor, the
30 input end of that new section must have a diameter larger
than that of the fiber core being repaired. On the other
hand, the output end of that new section must be reduced in
diameter relative to the fiber core being repaired. This
35 is often accomplished by tapering that output end of the

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new section using polishing. With laser applications, this produces undesirable diffusion through the sides of the taper, contributing to a buildup of heat and a loss of transmission efficiency.

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SUMMARY OF THE INVENTION

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One object of the present invention is to produce an optical waveguide for use in medical procedures which reduces to a minimum the loss of laser energy at the tip thereof.

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Another object of the invention is an optical waveguide as described above which eliminates heat generation conventionally found at any transmission interface between an optical fiber core and any focusing structure at the tip thereof.

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It is accordingly a related object of the present invention to eliminate heat shielding for medical personnel utilizing the optical waveguides described above and to produce a contact laser probe suitable for endoscopic use which does not require in complementary use therewith complicated and dangerous cooling systems that introduce additional alien materials into the body of the patient.

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It is a further object of the present invention to produce a contact laser probe as described above which is effective in endoscopic procedures on the inner walls of

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tubular passageways of the body, such as those of the circulatory, digestive, urological and respiratory systems.

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Still another object of the present invention is to produce a tip for focusing laser energy from the output end of an optical fiber which is free on the sides thereof from polishing abrasions, but which nevertheless focuses optical energy from the optical fiber in a pattern conducive to the medical procedure to be undertaken.

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In addition, it is an object of the present invention to produce a contact laser probe in which the index of refraction of the tip thereof is closely matched to the index of refraction of the fiber core with which it is used and with the tissue to be contacted.

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Furthermore, it is an object of the present invention to eliminate loose or lost focusing structures in contact laser probes.

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It is yet another object of the present invention to reduce the cost of manufacture of contact laser probes to such an extent as to render such products inexpensive enough to be disposable after a single use.

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Yet another object of the present invention is to simplify endoscopic medical laser procedures.

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Yet another object of the present invention is to eliminate undesirable tissue coagulation at the sides of the focussing tip in a contact laser probe.

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Yet an additional object of the present invention is to provide a laser surgeon with laser probes capable of transmitting laser energy in a variety of patterns each optimally suited toward various specific ends, such as cutting tissue, vaporizing tissue, or effecting hemostasis. It is intended to achieve these ends even where the site of the surgical procedure involved is laterally adjacent to the laser probe on the inner wall of a passageway in the body.

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Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims.

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To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, a contact laser probe is provided for coupling to a laser to transmit laser energy to a living tissue or other material for treatment according to a predetermined procedure. The probe comprises a fiber core formed of an optically transmissive material, and having an input end for receiving laser energy from the laser and an output end remote therefrom for delivering the laser energy to tissue to be treated according to a specified medical procedure.

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The optically transmissive material preferably has an index of refraction similar to that of the tissue to be treated.

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The probe further comprises an end structure of the same optically transmissive solid material integrally formed on the output end of the fiber core, generally from a molten portion thereof. The side surfaces of the end structure are free of polishing abrasions, thereby minimizing the diffusion of laser energy therethrough. This enables controlled focusing of the laser energy from the fiber core onto the tissue.

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In one preferred embodiment of the invention, the end structure comprises an axially aligned tip having sides that taper smoothly from a first end adjacent to the fiber core to a terminus at the second end, which is remote from the fiber core. That terminus comprises a flat surface disposed normal to the longitudinal axis of the fiber core. The tip in this embodiment may be generally described as being frustoconical in shape.

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In a preferred embodiment of the axially-aligned, tapered form and the invention, using a fiber core of about 600 microns in diameter the tip has a length in the range of about 1.5 millimeters to about 7.0 millimeters and a diameter at the terminus thereof in the range of about 75 microns to about 300 microns. Alternatively, the apex angle formed by projecting the sides of the tip to an

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intersection beyond the terminus is preferably in the range of about 4° to about 45°.

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Additionally, the disclosed invention includes a method for making an axially-aligned, tapered tip for an optical waveguide for use with a medical laser. In the method, a first portion of a length of fiber core of optically transmissive material located intermediate second and third portions of the fiber is heated to render the first portion molten. Thereafter, the third portion of the fiber core is drawn away from the heated first portion parallel to the longitudinal axis of the fiber, thereby to produce from the heated first portion a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from the second portion. The shape is cooled and scored at a point located a predetermined distance along the shape from the second portion of the fiber core. Finally, the shape is broken at the scoring point to form from the shape integrally with the second portion of the fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through the fiber core to the second portion thereof. The tip is polished to produce at the end remote from the second section of the fiber core a terminus comprising a flat surface disposed normal to the longitudinal axis of the fiber core.

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In another, off-axis tapered embodiment of the invention, the end structure comprises a generally cylindrical bend portion having a proximal end radially coextensive with the output end of the fiber core and a distal end opposite therefrom. The longitudinal axis of the distal end of bend portion diverts from the longitudinal axis of the output end of the fiber core at a predetermined bend angle. A tip is formed on the distal end of the bend portion having sides that taper from a first end adjacent to the bend portion of the end structure to a terminus at the second end, which is remote from the fiber core. The terminus comprises a flat surface which may be disposed normal to the longitudinal axis of the tip. Preferably, however, the terminus is disposed normal to the plane of the bend portion and parallel to the longitudinal axis of the fiber core at the output end thereof. The tip in this embodiment may be generally described as being frustoconical in shape. The optically transmissive material preferably has an index of refraction similar to that of the tissue to be treated.

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By bringing the terminus of the tip of the end structure into contact with the wall of a bodily vessel, laser energy may be accurately and directly transmitted to tissue in the wall of a bodily passageway despite the output end of the probe being disposed generally parallel thereto. If the terminus of the tip is pressed against or

1 into the tissue of the passageway, it has been found that
laser energy is transmitted from the tip into the
5 contacting tissue primarily along the side surface of the
tip that is located on the same side of the end structure
as is the inner side of the curved bend portion.
Naturally, in addition to being employable in a contact
10 mode, the tip can be backed off of the material receiving
treatment into a so-called diffused mode in which the laser
beam has decreasing intensity and an enhanced hemostatic
effect.

15 In a preferred embodiment of the tapered, off-axis
form of the invention, the predetermined bend angle at
which the longitudinal axis of the bend portion diverts
from the longitudinal axis of the output end of the fiber
20 core is in the range of about 15° to about 60° or more
preferably in the range from about 25° to about 45°. Using
a fiber core of about 600 microns in diameter the tip has
a length in the range of about 1.5 millimeters to about 7.0
25 millimeters and a diameter at the terminus thereof in the
range of about 75 microns to about 300 microns.
Alternatively, the apex angle formed by projecting the
30 sides of the tip to an intersection beyond the terminus is
preferably in the range of about 4° to about 45°.

Additionally, the disclosed invention includes a
method for making a tapered, off-axis end structure for an
35 optical waveguide for use with a medical laser. In the

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method, a first portion of a length of fiber core of
optically transmissive material located intermediate second
5 and third portions of the fiber is heated to render the
first portion molten. Thereafter, the first portion of the
fiber core is bent so that the longitudinal axis of the
third portion is at a predetermined angle to the
10 longitudinal axis of the second portion, creating the bend
section of the invention. The second portion is then
cooled, and a tip for narrowly focusing laser energy from
the medical laser is formed from the first portion of the
15 fiber core.

The tip is formed by processing the third portion of
the fiber core as described below. A first section of that
third portion located intermediate second and third
20 sections of the third portion is heated to render the first
section molten. The second section of the third portion is
located adjacent to the first portion of the fiber core
from which the bend section thereof was generated. Heating
25 steps may be accomplished through the use of an oxygen
acetylene flame, an electric arc, high frequency radio
signals, or the application of a laser.

30 Thereafter, the third section of the third portion of
the fiber core is drawn away from the heated first section
parallel to the longitudinal axis of the first portion of
the fiber core at the end thereof remote from the second
35 portion thereof. This produces from the heated first

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section a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from the second section. The shape is cooled and scored at a point located a predetermined distance along the shape from the second portion of the fiber core.

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Finally, the shape is broken at the scoring point to form from the shape integrally with the second section of the third portion of the fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through the fiber core to the second portion thereof. The tip is polished to produce at the end remote from the second section of the fiber core a terminus comprising a flat surface disposed normal to the plane defined by the second and third sections of the first portion or the first section of the third portion of the fiber core, but parallel to the longitudinal axis of the fiber core.

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In one embodiment of the invention, the end structure is an orbicular, axially aligned structure that comprises a lens portion disposed at the output end of the fiber core concentric with its longitudinal axis and a transition portion smoothly connecting the surface of the lens portion to the sides of the fiber core. Typically, the lens portion is orbicular, or spherical, having a diameter that is greater than the diameter of the fiber core.

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The end structure functions in two distinct operative modalities. In the carrier mode of transmission, a portion

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of the laser energy corresponding to low order rays of
laser energy delivered from the output end of the fiber
5 core are focused through a fast focal point aligned with
the longitudinal axis of the fiber core at the output end
thereof. As used herein and in the appended claims, the
portion of the laser energy corresponding to low order rays
10 that is focused through the fast focal point will be
referred to as a "second portion" of that laser energy.
This modality of transmission is operative under all
conditions, whether or not the end structure is in contact
15 with tissue to be treated according to a medical procedure.

Nevertheless, when the end structure is brought into
contact with such tissue, an avalanche mode of transmission
results in which multi-directional laser energy is
20 transmitted through such portions of the surface of the end
structure as make contact with the tissue. The multi-
directional laser energy transmitted in this manner
corresponds to high order rays of laser energy delivered
25 from the output end of the fiber core into the lens portion
of the end structure. There such high order rays of laser
energy become internally star-reflected about the inside of
the lens portion forming a region of multi-directional
30 laser energy. This multi-directional laser energy is then
available for transmission in the avalanche mode through
any portion of the surface of the end structure which
35 contacts the tissue to be treated. As used herein and in

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the appended claims, the portion of the laser energy corresponding to high order rays that are internally star-
reflected in the lens portion of the structure will be
referred to as a "first portion" of that laser energy.

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Due to the enlarged size of the lens portion of the end structure relative to the fiber core, the laser energy transmitted in the avalanche mode of transmission can thus be applied to a large area of the tissue simultaneously, a transmission pattern which is effective in rapid vaporization of large volumes of tissue, while producing very desirable hemostasis characteristics. The orbicular structure is thus an ideal contact laser probe tip for vaporizing larger areas of tissue that are contacted by the laser probe tip itself.

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In a preferred embodiment of the invention, the diameter of the lens portion is in the range of about 0.6 millimeters to about 3.0 millimeters, or more preferably in the range of from about 0.8 millimeters to about 2.5 millimeters. Using a fiber core of about 1.0 millimeters in diameter, the lens portion has a diameter of about 1.2 millimeters.

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Additionally, the disclosed invention includes a method for making such an axially aligned orbicular end structure from optical waveguide for use with a medical laser. In the method, the end of an optical fiber is oriented in a generally vertical direction and rotated

1 about the longitudinal axis thereof. A first portion of
the length of the fiber adjacent to the end thereof is
5 heated, thereby rendering it molten. The heated portion of
the fiber core is permitted to assume a bulbous shape
having smoothly flaring sides and a diameter that is
greater than the diameter of the fiber. The bulbous shape
10 is then cooled. In the heating step the end of the optical
fiber core is oriented downwardly at an inclination angle
to the vertical in the range of from about 10% to about
15%.

15 In another orbicular embodiment preferred invention
that has an off-axis configuration, the end structure
comprises a generally cylindrical bend portion having a
proximal end radially coextensive with the output end of
20 the fiber core and a distal end opposite therefrom. The
longitudinal axis of the distal end of bend portion diverts
from the longitudinal axis of the output end of the fiber
core at a predetermined bend angle. A lens portion is
25 disposed at the distal end of the bend portion
concentrically with the longitudinal axis thereof and
joined to the bend portion by a transition portion smoothly
connecting the surface of the lens portion to the sides of
30 the distal end of the bend portion. The lens portion is
orbicular or spherical and is of a diameter greater than
the diameter of the distal end of the bend portion. The
35 resulting off-axis embodiment also transmits laser energy

1 in both the carrier and avalanche modalities of
transmission and is particularly useful in applying laser
5 energy to a broad section of tissue located on the interior
of a body passageway immediately adjacent to the laser
probe itself. In yet another embodiment of the off-axis
orbicular embodiment of the invention, the length of the
10 bend portion is typically in the range of about 0.5
millimeters to about 1.5 millimeters.

Additionally, the disclosed invention includes a
method for making an end structure for the orbicular off-
15 axis laser tip. In the method, the steps already described
for producing an axially aligned orbicular end structure
are first followed. Thereafter, a second portion of the
length of the fiber core located intermediate and adjacent
20 to the first portion and a third portion of the fiber core
is heated rendering it molten. The second portion of the
fiber core is then bend so that the longitudinal axis of
the end thereof adjacent the first portion of the fiber
25 core diverges at a predetermined angle from the
longitudinal axis of the third portion of the fiber core.
Heating in all instances may be accomplished through the
30 use of an oxygen acetylene flame, an electric arc, high
frequency radio signals, or the application of a laser.

In an alternate embodiment of the invention, a tip is
provided for the end of an optical laser fiber core that is
35 integrally formed therewith and has sides that flare

1 smoothly and without polishing abrasions from that first
end to a terminus at a second end remote from the fiber
core. The tip takes on a generally bulbous shape with
5 sides that smoothly merge into the sides of the fiber core
and terminate at the end remote from the fiber core in a
flat surface or terminus disposed normal to the
10 longitudinal axis of the fiber core. The diameter of the
terminus is greater than the diameter of the fiber core
itself. The tip may also be described as being generally
hemispherical in shape. It may be located at either the
15 input end of the fiber core to facilitate its optical
coupling with the output of another, or at the output end
thereof in order to produce a beam of outgoing laser energy
of a diameter larger than that which would result from a
20 naked optical fiber core of the same diameter.

In making the bulbous or hemispherical tip described
above, the end of the optical fiber core is oriented in a
25 vertical direction and a first portion of the length of the
fiber core adjacent to that end is heated to render that
first portion molten. Maintaining the vertical orientation
of the fiber core, the heated first portion is permitted to
30 assume a bulbous shape having smoothly flaring sides and a
maximum diameter taken normal to the longitudinal axis of
the fiber core that is greater than the diameter of the
fiber core itself. Thereafter, the shape is cooled, and
35 the end thereof remote from the fiber core is removed,

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generally by polishing, to produce a flat surface or
terminus disposed normal to the longitudinal axis of the
5 fiber core.

BRIEF DESCRIPTION OF THE DRAWINGS

10 In order that the manner in which the above-recited
and other advantages and objects of the invention are
obtained, a more particular description of the invention
briefly described above will be rendered by reference to
the specific embodiments thereof which are illustrated in
15 the appended drawings. Understanding that these drawings
depict only typical embodiments of the invention and are
therefore not to be considered limiting of its scope, the
invention will be described with additional specificity and
20 detail through the use of the accompanying drawings in
which:

Figure 1 is an elevation view of one embodiment of a
25 contact laser probe, including an optical waveguide,
incorporating teachings of the present invention;

Figure 2 is an enlarged, detail elevation view of a
first embodiment of the tip portion of the optical
30 waveguide shown in Figure 1;

Figure 3 is an enlarged, detail elevation view of a
second embodiment of the tip portion of the optical
waveguide shown in Figure 1;

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Figures 4A-4G are a sequence of illustrations depicting a method for manufacturing the tip portions of optical waveguides illustrated in Figures 2 and 3;

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Figures 5A-5E illustrate alternative embodiments of a contact laser probes that incorporate teachings of the present invention;

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Figures 6 is a third embodiment of a tip for an optical waveguide incorporating teachings of the present invention;

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Figures 7A-7F are a sequence of illustrations depicting a method for manufacturing the tip portion of an optical waveguide illustrated in Figure 6;

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Figure 8 is an enlarged, detail elevation view of a first embodiment of an off-axis end structure for an optical waveguide, such as is shown in Figure 1;

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Figure 9 is an enlarged, detail elevation view of a second embodiment of an off-axis end structure for the optical waveguide shown in Figure 1;

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Figure 10 is an enlarged, detail elevation view of a third embodiment of an off-axis end structure for the optical waveguide shown in Figure 1;

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Figure 11 is a graph of the transmission percentage for off-axis structures such as those shown in Figures 8-10 varying as a function of the bend angle corresponding thereto;

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Figures 12A-12G are a sequence of illustrations depicting a method for manufacturing the end structures of optical waveguides illustrated in Figures 8-10;

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Figure 13 is an enlarged, detail elevation view of an axially aligned orbicular end structure for the optical waveguide shown in Figure 1;

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Figure 14 is a schematic view of the lens portion of the end structure of Figure 13 illustrating selected optical characteristics thereof;

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Figure 15 is an enlarged schematic view of the lens portion of the end structure of Figure 13 is in contact with tissue illustrating selected optical characteristics thereof; Figure 16 is an enlarged, detail elevation view of an off-axis orbicular end structure for the optical waveguide shown in Figure 1; and

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Figures 17A-17E are a sequence of illustrations depicting a method for manufacturing the end structures of the orbicular optical waveguides illustrated in Figures 13 and 16.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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Shown in Figure 1 is a laser probe 10 for coupling to a medical laser (not shown) to be used in medical procedures. Laser probe 10 functions as an optical waveguide for precisely transmitting laser energy from the

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medical laser to tissue to be treated according to prescribed medical procedures.

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Toward this end, laser probe 10 includes a optical fiber composite 12 containing a core of optically transmissive material and having an input end 14 for receiving laser energy and an output end 16 remote therefrom for delivering the laser energy to the tissue to be treated. At input end 14 of optical fiber composite 12, laser probe 10 is provided with a fitting 18 having an input end 20 to be coupled to a medical laser to receive laser energy therefrom. The laser source coupled to laser probe 10 may include any of the medical lasers described above. A protective cap 22 is used to cover input end 20 of fitting 18 when laser probe 10 is not coupled to that medical laser source.

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For the ease and convenience of a medical practitioner using laser probe 10, optical fiber composite 12 between input end 14 and output end 16 thereof is a flexible structure through which laser light is transmitted by internal reflectants within a fiber core concentrically surrounded by successive layers of other materials. A typical form of these layers will be discussed subsequently in relation to Figure 2. At output end 16 optical fiber composite 12 is encased in a cladding 24, generally comprised of needle stock. A fixed handle 26 is provided surrounding cladding 24 to afford an easy purchase on laser

1 probe 10 and to permit the laser energy transmitted therein
to be directed to the correct tissue to be treated. The
5 tip 28 of optical fiber composite 12, which protrudes from
the end of cladding 24 remote from fitting 18, comprises
the actual structure through which such a laser energy is
applied to tissue. A protective sheath 30 is used to cover
10 tip 28 when not in use.

A first embodiment of a tip 28 for the optical
waveguide shown in Figure 1 is illustrated in enlarged
detail in Figure 2. There, optical fiber composite 12 can
15 be seen to be comprised of a fiber core 38 coaxially
surrounded by a layer of hard cladding 40, which is in turn
surrounded by a flexible reinforcing jacket 42. In medical
situations, fiber core 38 is usually approximately 600
20 microns in diameter, although for special applications
diameters of 200 microns, 400 microns, or 1000 microns are
used. Fiber core 38 is generally composed of an optically
25 transmissive material, such as quartz, silica, or a
thermoplastic, for example polycarbonate. These materials
not only readily transmit light, but are amorphous,
contributing to their easy formation into the cylindrical
30 shape of the typical fiber core. A fiber core comprised of
these materials has a refractive index of about 1.45.
Fiber core 38 is surrounded by a cladding 40 made of a
polymer which has a lower refractive index than fiber
35 core 38, thereby causing the interval reflectiveness of the

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composite. Cladding 40 also protects fiber core 38 from environmental degradation, thus maintaining its strength.

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Finally, a reinforcing jacket 42 made of a plastic material, such as teflon or nylon, is added on the outside of hard cladding 40 to protect both hard cladding 40 and fiber core 38 from environmental conditions.

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To achieve maximum effectiveness in transmitting laser energy through optical fiber composite 12 to a tissue to be treated in a medical procedure, the output end of fiber core 38 is provided with a focusing structure that directs
15 emerging laser light into a pattern conducive to the medical procedure being undertaken.

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Accordingly, in the present invention means are formed integrally with fiber core 38, and from the same material
25 thereas, for narrowly focusing laser energy from output end 16 of optical fiber composite 12. As shown in Figure 2 by way of example and not limitation, tip 28 on the output end of fiber core 38 is rotationally symmetric and has
30 sides 44 which taper smoothly from a first end 46 of tip 28 to a terminus 48 at a second end 50 of tip 28 remote from fiber core 38. Due to the manner in which tip 28 is
35 formed, sides 44 thereof are free of polishing abrasions, thereby minimizing the diffusion of laser energy therethrough and directing an optimum amount of such energy from fiber core 38 through terminus 48 of tip 28.

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Figure 48 comprises a flat surface disposed normal to the longitudinal axis of fiber core 38.

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Where fiber core 38 is approximately 600 microns in diameter, the diameter D of terminus 48 will be in the range of about 10 microns to about 300 microns, depending upon the extent of focusing required in tip 28. The length L of tip 28 from first end 46 thereof to terminus 48 is typically in the range of about 1.5 millimeters to about 7.0 millimeters. If sides 44 of tip 28 are projected in a direction away from fiber core 38 to intersect at a point P, an apex angle A is defined having the vertex at point P and sides coincident with sides 44. In tip 28 the measure of apex angle A is in the range of about 4° to about 45° or more preferably in the range of about 9° to about 20°.

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As seen in Figure 2, tip 28 has a terminus 48 which is a substantial fraction of the diameter of fiber core 38. When the length L of tip 28 is relatively short, then apex angle A has a measure in the upper portion of the range quoted therefor above.

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This relative configuration is, however, subject to variation as evidenced by the appearance of a second embodiment of a tip 60 for laser probe 10 shown in Figure 1. There, the diameter D₁ of terminus 48 is relatively small compared to the diameter of fiber core 38, while the length L₁ of tip 60 is elongated relative to the same dimension of tip 28 in Figure 2. As a result the measure

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of the apex angle A_1 formed by extending sides 44 away from optical fiber composite 12 to a point of intersection (not shown) is in the lower end of the range therefor mentioned above.

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While the above ranges of physical dimensions in the inventive tip are based on a tip integrally formed with a fiber core having a diameter of about 600 microns, fiber cores for medical and other uses having both larger and smaller diameters will be enhanced when provided with tips formed according to the principals of the present invention. It should be understood that in such instances, appropriate adjustments to the dimensions of such inventive tips are to be expected and are considered to be within the scope of the present invention.

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For example, utilizing a fiber core having a diameter of about 200 microns, tip lengths in the range of about 1.0 millimeters to about 1.5 millimeters with a terminus diameter in the range of about 10 microns to about 100 microns would be typical. The apex angle A in such devices would be in the range of about 4° to about 45° , or more preferably in the range of about 6° to about 20° . On the other hand, for a fiber core having a diameter of about 400 microns, tip lengths in the range of about 1.0 millimeters to 2.0 millimeters and terminus diameters in the range of about 10 microns to about 200 microns would be typical. Such devices would have an apex angle A with a measure in

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the range of about 4° to about 45° , or more preferably in the range of about 11° to about 20° .

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Alternatively, fiber cores with larger diameters can also be benefited by tips integrally formed therewith according to the teachings of the present invention. For example, a fiber core with a diameter of about 1000 microns would have a tip length in the range of about 1.5 millimeters to about 10.0 millimeters and a terminus diameter in the range of about 10 microns to about 700 microns. These devices would have an apex angle A having a measure in the range of about 4° to about 45° , or more preferably in the range of about 8° to about 20° .

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The amount of laser energy that is transmitted out of tips 28 or 60 through terminus 48 thereof is determined by a number of factors. These include the amount of laser energy lost in fiber core 38 during transmission from input end 14 to output end 16 thereof, the shape of tips 28 or 60, the refractive index of the material of which those tips are made, and the refractive index of the tissue to which the tips are applied.

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Assuming that a fiber core is made of quartz or silica, which has a refractive index of 1.45, and that fiber core 38 is not tapered as in Figures 2 and 3, but has a highly polished, flat end normal to the longitudinal axis of the fiber core 38, then only about 4 percent of the laser energy transmitted through fiber core will be

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reflected backwards thereinto when the flat end is in air,
which has a refractive index of 1.00. The remaining 96
5 percent of the laser energy will be transmitted into the
air through the flattened end of the tip.

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If, however, a focusing tip is used with the fiber
core, the tip will have higher refractive index than the
fiber core. For sapphire, the refractive index is 1.80; for
diamond it is 2.60. In addition, an air gap will
necessarily arise between the fiber core and the tip
producing a double transmission interface for laser energy
15 passing from the fiber core to and through the tip. Such
laser energy will experience not only the above-described
4% backwards reflection when passing from the fiber core
into the air gap, but will be further degraded by 8% in the
20 case of sapphire and about 12% in the case of diamond when
passing from that air gap into the tip itself.

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Additionally it must be pointed out that for use in
connection with living tissue, the refractive index of
quartz or silica is very close to that of the material to
which laser energy is ultimately to be delivered. This is
not the case when a focusing tip of, for example, sapphire
30 or diamond, is employed. Then, an additional transmission
interface between the tip and the material to which laser
energy is to be delivered further dissipate that energy.
The amount of laser energy transmitted will also decrease

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if the tip of the optical fiber core is rough, dirty or polished.

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When formed according to the principles of the present invention, tips 28 and 60 are by contrast integral parts of fiber core 38. A principal advantage of this structure is the elimination of light losses that occur in prior art devices at the interface between the output end of an optical fiber core and the focusing structure or tip used therewith. The cause of these energy losses has been discussed above.

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Tips 28 and 60 with a converging frustoconical shape and a terminus 48 that is normal to the axis of fiber core 38 focuses light down tapering sides 44 of tips 28 and 60 to emerge therefrom through interface 48. This is due to the smooth taper found in tips 28 and 60 and to the absence on sides 44 thereof of polishing abrasions. In addition, the absence of cladding 40 about the sides of tips 28 and 60 increases the internal reflectiveness of this portion of the laser probe. This effect arises because the refractive index of cladding 40 is less than that of the air surrounding the sides of tips 28 and 60 when cladding 40 has been removed therefrom. The resulting greater difference in refractive indexes causes laser energy traveling through tips 28 and 60 to be more readily reflected internally from the sides thereof than if cladding 40 were wrapped thereabout.

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As a result, most laser energy transmitted through fiber core 38 is focused out of terminus 48 in the shape of a small diverging cone. Some of the laser energy will, nevertheless, reflected backup optical fiber composite 12 due to the mismatch between the refractive index of the material making up fiber core 38 as well as tip 28 or 60 and the refractive index of air. When tip 28 is placed in contact with a tissue, however, laser energy is coupled out of terminus 48 directly into the tissue with a minimum of reflection, as the refractive index of tip 28 closely resembles the refractive index of 1.45 ± 0.05 associated with the tissue.

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Figures 4A-4G are a series of illustrations depicting the steps for making a tip for an optical waveguide, such as tip 28 of Figure 2 or tip 60 of Figure 3. Initially, Figure 4A shows an end 70 of optical fiber composite 12 dimensioned suitably for use in medical laser procedures and constructed in concentric layered fashion as illustrated in and described above in relation to Figures 2 and 3. To produce a tip for optical fiber composite 12, such as tip 28 of Figure 2 or tip 60 of Figure 3, reinforcing jacket 42 on the exterior thereof is removed to reveal the layer of hard cladding 40 thereunder as shown in Figure 4B. Thereafter, substantially all of hard cladding 40 thereby exposed is removed by precleaning to reveal a first portion 72 of optical fiber core 38 therewithin.

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First portion 72 is located intermediate and adjacent to a second portion 74 and a third portion 76 at end 70 of fiber core 38. Precleaning may be effected by exposing the portion of cladding 40 overlying first, second, and third portions 72, 74, 76 respectively, of fiber core 12 to a flame, by mechanical stripping, or by washing the same portion of hard cladding 40 in an acetone bath followed by drying.

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Optical fiber composite 12 is then placed in a jig comprised of a tube 78 made, for example, of metal or a ceramic and having an internal diameter that achieves a friction fit with the outer surface of optical fiber composite 12. The assembly is aligned vertically with end 70 of fiber core 38 pointing downwardly. A force F shown schematically in Figure 4D is applied to third portion 76 of fiber core 38 in a manner that places first portion 72 under tension in a direction parallel to the longitudinal axis thereof. Thereafter, heat H is applied to first portion 72 until first portion 72 is rendered molten.

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The step of applying heat to first portion 72 can be accomplished by exposing first portion 72 to an electric arc. It is preferable that in creating an electric arc for this purpose in contrast to conventional equipment used in the field of optical fiber shaping, the equipment produce, not a focused electric arc, but one having a broad width relative to the length of first portion 72. In this manner

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a substantial length, rather than a focused point, of fiber core 38 becomes heated. To do so it is necessary to appropriately configure the electrodes producing the electric arc and to appropriately position those electrodes relative to the first portion 72. Typically, this is accomplished by using electrodes which are elongated and parallel to the longitudinal axis of fiber core 38 and then positioning those electrodes on opposite sides of first portion 72 relatively remotely therefrom.

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In addition heating can occur using an oxygen acetylene torch, radiant heat tunnels, high frequency radio signals, or laser energy itself as generated, for example, by a carbon dioxide laser. During the heating of first portion 72, metal tube 78 besides functioning as a jig to support optical fiber composite 12, also shields portions of optical fiber composite 28 remote from first, second, and third portions 72, 74, 76, respectively, from heat, thereby functioning as a cylindrical heat sink.

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As first portion 72 becomes molten and ceases to be rigid, force F draws third portion 76 away from section portion 74 parallel to the longitudinal axis of fiber core 38. As a result, and as seen in Figure 4E, from the heated molten first portion 72 a shape 80 is produced having at the end thereof adjacent to second section 74 smoothly tapering sides and a lateral cross section decreasing with the distance from second portion 74. Typically a force F

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of several grams is used in relation to a fiber core 38 having a diameter of 600 microns. Nevertheless, the size of force F may be varied to yield frustoconical shapes, such as shape 80, having different relative proportions. Metal tube 78 may be removed at any point after shape 80 has cooled.

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After shape 80 has cooled, it is scored at a scoring point 83 located a pre-selected distance along shape 80 from second portion 74. Shape 80 is broken at scoring point 82 to form from the end thereof adjacent to second portion 74 a tip 28 for narrowly focusing laser energy transmitted through fiber core 38. The distance of scoring point 83 from second portion 74 will determine, not only the length, but the size of the terminus of any resulting tip.

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Tip 28 is thus integrally formed with fiber core 38 from the same optically transmissive material of which fiber core 38 is made. The result is a tip 28 with a terminus 48 at the end thereof remote from optical fiber composite 12 which is a flat surface disposed normal to the longitudinal axis of optical fiber composite 12. Terminus 48 may be flattened by mechanical polishing and then fire polished to remove stress cracks at scoring point 82.

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In the configuration of laser probe 10 shown in Figure 1, tip 28 and the portion of cladding 24 adjacent thereto extend a relatively short distance from handle 26

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in alignment with the longitudinal axis thereof. Such an arrangement is conducive to a tool that may be utilized for general surgical purposes. Nevertheless, Figures 5A-5E depict alternate arrangements having special medical procedures in mind.

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For example, Figure 5A illustrates a laser probe 86 in which the end of cladding 24 adjacent to tip 28 has been bent out of alignment with the longitudinal axis of handle 26 at an acute angle B_1 . This enables the tool illustrated to be used in oral procedures.

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In Figure 5B a laser probe 88 has cladding 24 that projects from handle 26 for an extended distance in the range of about 320 millimeters to 480 millimeters in alignment with the longitudinal axis of handle 26 and may thus be used for laparoscopic applications.

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Figure 5C illustrates a laser probe 90 in which cladding 24 has been bent away from the longitudinal axis of handle 26 at angle B_2 , but this occurs at a point closer to the end of handle 26 than occurs, for example, in laser probe 86 in Figure 5A. The portion of cladding 24 beyond the bend therein can be extended up to 90 to 100 millimeters so that the device shown in Figure 5C will function conveniently in nasal procedures.

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In laser probe 92 shown in Figure 5D, cladding 24 has been bent twice in succession in compensating directions, so as to be offset from but parallel to the longitudinal

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axis of handle 26. Such devices find application in neural surgery.

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Finally, Figure 5E illustrates a laser probe 94 suitable for use in a laryngology procedure. In laser probe 94 cladding 24 has been angled away from the longitudinal axis of handle 26 at an angle B_3 greater than angle B_1 shown in Figure 5A or angle B_2 shown in Figure 5C. The portion of cladding 24 beyond the bend point may extend a distance of up to about 300 millimeters.

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The frustoconical tip produced by the method of the present invention results in a contact laser probe having reduced transmission losses at the tip thereof. Because the tip and fiber core are made of the same material, and are integrally formed one with another, no transmission interface therebetween contributes to transmission losses and undesirable heat, as in known devices utilizing fiber cores and focusing tips distinct therefrom. Secondly, as the fiber core and the tip formed thereon are of the same material, and because the refractive index of optical cores is typically quite similar to that of tissue to be treated in medical laser procedures, laser energy dissipation at the interface between the tip and the tissue produces substantially less refraction losses than with medical laser probes having distinct fiber cores and tips. Finally, because the sides of the frustoconical tip of the present invention are not formed by polishing, they are

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free of abrasions and do not tend to diffuse laser energy therethrough.

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The reduced laser energy losses with the inventive tip eliminate the need for shielding for medical personnel and in endoscopic uses eliminates the need for auxiliary cooling systems and the safety risks associated therewith.

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The result is an optical waveguide for efficiently and precisely transmitting laser energy from a medical laser to the tissue to be treated according to a medical procedure. Complicated methods of attaching the tip for the waveguide to the fiber core thereof are eliminated, as are the problem of loose or lost probe tips, and disposability of the device is enabled due to its reduced cost of manufacture.

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The effectiveness of the tip configuration shown in Figures 2 and 3 in avoiding the build-up of heat have been confirmed by direct testing, which is reported below.

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Example 1. A frustoconical tip such as that shown in Figures 2 and 3 having a length L of 7.0 millimeters and a diameter D for the terminus thereof of approximately 100 microns was tested to determine the percent of laser energy transmitted therethrough into water. Each tip was subjected to a maximum power of 6.6 watts for various numbers of exposures at selected times and was then inspected for any adverse effects, such as darkening,

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chipping, or deformation due to heat. The following test results were observed:

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TABLE I

	Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
10	1	89	9.0	2	None
	2	90	9.0	2	None
	3	81	9.0	2	None
	4	86	9.0	2	None
15	5	89	9.0	2	None
	6	85	9.0	2	None
	7	84	9.0	2	None
20	8	93	0.5	6	None*
	9	92	2.5	6	None
	10	88	9.0	1	None

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*Fiber tip chipped due to being dropped on floor. Test continued.

Mean % Transmission in water: 88%

Power Source: Visible multiline argon laser, 6.6W maximum power.

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Measurement: Laserguide Model 2015 integrating sphere power meter calibrated for visible multiline argon.

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Two advantageous results are apparent in relation to prior art devices such as sapphire tips used in combination with conventional fiber cores. First, the mean

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transmission percentage is much improved in relation to such prior art devices. Secondly in such prior art devices substantial quantities of laser energy are dissipated as heat which would otherwise be expected under the circumstances in which the above test was conducted to result in tip destruction.

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Example 2. Subsequently, a probe tip of frustoconical configuration constructed according to the teachings of the present invention having a tip length L in the range of about 1.5 to 2.0 millimeters and a diameter D at the terminus thereof of about 100 microns was tested for percent power transmission in water and subjected to a maximum power test at 8.4 watts for various numbers of various exposure times. The results observed appear below:

TABLE II

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	90	20	2	None
2	90	20	2	None
3	88	20	2	None
4	88	20	2	None
5	90	20	2	None
6	91	20	2	* None

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(Continued on following page)

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TABLE II
(continued)

5	Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
	7	88	20	2	None
10	8	91	20	2	None
	9	91	20	2	None
	10	91	20	2	None
	11	90	20	2	None
15	12	90	20	2	* None
	13	91	20	2	None
	14	91	20	2	None
	15	90	60	2	None
20	16	90	60	2	None
	17	88	120	2	None
	18	90	180	2	None

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*Fiber showed slight chip prior to testing. These fibers were not rejected to see how slight damage would affect transmission.

Mean Transmission Percent in Water: 90%

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Power Source: Visible multiline argon laser, 8.4W maximum power.

Measurement: Laserguide Model 2015 integrating sphere power meter calibrated for visible multiline argon; Lexel power meter.

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Once again, in contrast to composite prior art devices in which a tip and a fiber core having differing refractive indices are used in combination, the inventive tips for which test data is recorded above had a advantageously high mean transmission percentage in water of 90 percent, and no visually detectable evidence of heat damage was observed.

Example 3. In an additional test, a tip, such as that illustrated in Figures 2 and 3 having a length L in the range of about 1.5 to 2.0 millimeters and a diameter D at the terminus thereof of about 100 microns was tested at 8.5 watts for transmission percent in water. In addition each tip involved was tested at the extremely high power of 75 watts for a single exposure of 20 seconds and inspected for visual evidences of heat damage. The results are shown below:

TABLE III

<u>Sample</u>	<u>Percent Transmission (in water)</u>	<u>Exposure Time (in seconds)</u>	<u>No. of Exposures</u>	<u>Tip Visual Changes</u>
1	85	20	1	None
2	85	20	1	None
3	87	20	1	None
4	88	20	1	None
5	89	20	1	None
6	88	20	1	None

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TABLE III
(continued)

5	<u>Sample</u>	<u>Percent Transmission (in water)</u>	<u>Exposure Time (in seconds)</u>	<u>No. of Exposures</u>	<u>Tip Visual Changes</u>
	7	87	20	1	None
	8	85	20	1	None
10	9	88	20	1	None
	10	88	20	1	None
	11	87	20	1	None
	12	87	20	1	None
15	13	87	20	1	None
	14	87	20	1	None
	15	86	60	1	None
	16	87	60	1	None
20	17	88	120	1	None

Mean Transmission Percent in Water: 87%

Power Source: Quantronix 117 laser, maximum power used 75W.

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Measurement: Coherent power meter.

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An advantageously high mean transmission percent in water of 87 percent was observed. Despite power exposures which would have destroyed prior art composite tip-and-fiber core combinations, the inventive tips tested above were undamaged. Figure 6 illustrates a third embodiment of a tip 100 embodying teachings of the present invention.

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Tip 100 can be seen to be integrally formed with fiber core

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38 of an optical fiber composite 12 configured as
illustrated and described previously in relation to Figures
5 2 and 3. Tip 100 is rotationally symmetric and radially
coextensive at a first end 102 thereof with fiber core 38.
In contrast to the frustoconical embodiments illustrated in
Figures 2 and 3, however, tip 100 has sides 104 that flare
10 smoothly from first end 102 to an enlarged terminus 106 at
second end 108 remote from fiber core 38. Similarly,
however, to the two frustoconical embodiments 28 and 60
shown in Figures 2 and 3, respectively, the outer surface
15 of sides 104 of tip 100 are free from polishing abrasions.
This is due to the manner to be described below in which
tip 100 is formed and results in the minimizing of the
diffusion of laser energy through sides 104.

20 In general terms, tip 100 assumes a bulbous shape
having a maximum diameter D_3 taken normal to the
longitudinal axis of fiber core 38 which is greater than
the diameter of fiber core 38 itself. The bulbous shape
25 terminates at second end 108 in a flat surface or terminus
106 disposed normal to the longitudinal axis of fiber core
38. Alternatively, tip 100 can be described as comprising
30 a generally hemispherical shape, the planar surface of
which functions as the terminus of tip 100. For a fiber
core 38 having a diameter of approximately 600 microns, the
diameter D_3 of terminus 106 of tip 100 is in the range of
35 from about 600 microns to about 800 microns.

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Tip 100 exhibits advantageous properties. First, if placed at the output end of an optical fiber core and used in a non-contact maneuver to deliver laser energy to tissue or another material, tip 100 serves to produce a pattern of laser energy discharge corresponding to an optical fiber core having a diameter larger than the optical fiber core with which tip 100 is integrally formed. This result has been achieved previously only through the use of focusing structures distinct from the optical fiber core itself, and consequently afflicted by the drawbacks inherent therein as described above.

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In addition, however, it has been found that in coupling one optical fiber core to another it is necessary that the end of the fiber core from which laser energy is being transmitted be smaller than the input end of the receiving fiber core optically coupled thereto. Where a series of couplings are required, each successive section of fiber core is, therefore, necessarily larger in diameter than that which preceded it. In the alternative each fiber core output end has been tapered by polishing it into a terminus having a diameter smaller than the fiber to which it is attached.

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Both alternatives have disadvantages. In the former, the successive enlargement of fiber optic cores leads to a pattern of laser energy discharge which is broader than and more diffused than the laser output that would have been

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1 removed from end 70 of optical fiber composite 12 to reveal
hard cladding 40 thereunder, as shown in Figure 7B.
5 Thereafter, precleaning is conducted in which hard cladding
40 is removed from overlying a first portion 120 of fiber
core 38 located at end 70 thereof to produce the
configuration shown in Figure 7C. Precleaning in this
10 instance can take any of the forms already described in
relation to Figures 4A-4G.

Optical fiber composite 12 is then secured in a jig
comprising a metal tube 78 capable of effecting a friction
15 fit with the outside surface of optical fiber composite 12,
and end 70 thereof is oriented in a vertical direction.
Heat H is then applied to first portion 120 to render first
portion 120 molten. The heating of first portion 120 can
20 be accomplished in any of the manners of heating described
in relation to Figures 4A-4G. Maintaining the vertical
orientation of fiber core permits the heated first portion
120 to assume a bulbous shape 122 shown in Figure 7E as
25 having smoothly flaring sides 104 and a maximum diameter
taken normal to the longitudinal axis of fiber core 38 that
is greater than the diameter of fiber core 38 itself.
30 Bulbous shape 122 is then cooled and the end 124 thereof
remote from fiber core 38 is removed to produce a flat
surface or terminus 106 normal to the longitudinal axis of
fiber core 38.

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In Figure 8 is shown a first embodiment of an off-axis end structure 130 capable of focusing laser energy at an angle to the longitudinal axis of the output end of an optical fiber. With this capacity, end structure 130 is of particular utility in focusing laser energy emerging from the output end of a medical laser probe waveguide on the wall of a bodily passageway in which the waveguide is disposed. End structure 130 can be seen to be integrally formed with fiber core 38 of an optical fiber composite 12 configured as illustrated and described previously in relation to Figures 2 and 3.

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According to one aspect of the present invention, means are provided for narrowly focusing laser energy from fiber core 38 onto portions of tissue off-set laterally from longitudinal axis Y-Y thereof. As shown by way of example and not limitation in Figure 8, off-axis end structure 130 comprises a generally cylindrical bend portion 132 and a tip 134 formed on the distal end thereof. Bend portion 132 has a proximal end radially coextensive with fiber core 38 at the output end thereof. The longitudinal axis Z-Z of bend portion 132 at the distal end thereof, which is also the longitudinal axis of tip 134, diverts from longitudinal axis Y-Y of the output end of optical fiber core 38 at a predetermined bend angle B.

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Tip 134 is generally rotationally symmetric and radially coextensive at a first end 136 thereof with bend

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portion 132. Tip 134 has sides 138, 140 that taper
smoothly from first end 136 to a terminus 142 that is a
5 flat surface disposed normal to the plane of bend portion
132 and parallel to longitudinal axis Y-Y of fiber core 38
at the output end thereof. The terminus, such as terminus
142 in the present invention, need not, however, assume
10 this orientation exclusively. The outer surface of
sides 138, 140 are free from polishing abrasions due to the
manner to be described below in which off-axis end
structure 130 is formed. This results in the minimizing of
15 the diffusion of laser energy through sides 138, 140.

In general, it has been discovered that laser energy
projected along optical fiber core 38 has a tendency to be
reflected off the inside of sides 138, 140 so as to be
20 directed through tip 134 and out thereof by way of
terminus 142. Surprisingly, only minor amounts of laser
energy are refracted out of tip 134 through side 140 on the
surface of tip 134 adjacent the curve outer surface of bend
25 portion 132. This advantageously leaves side 140 of
tip 134 cool enough to not damage tissue with which it
makes inadvertent contact. When optical fiber 12 is
30 disposed inside a tubular body passageway, it is thus
possible using bend structure 130 to focus laser energy on
the walls of such a passageway in the immediate vicinity of
the output end of fiber core 38, and conduct orthoscopic
35 laser procedures without the need to use bulky and

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expensive auxiliary equipment. Even more significantly,
however, this can be accomplished efficiently, without
generating excessive and potentially dangerous heat.

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It has also been found that if pointed second end 144
of tip 134 is pressed against or into a bodily tissue,
laser energy exits therefrom and enters that tissue through
side 138 of tip 134, which is adjacent to the inner
surface 146 of bend portion 132, enhancing the cutting
capacity of end structure 130 when used in the contact
mode.

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As will be illustrated in relation to Figure 11, the
measure of bend angle B can range upwardly to
approximately 90°, but preferably is in the range from
approximately 15° to approximately 60°, or more preferably
in the range from approximately 25° to approximately 45°.

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Due to the manner in which bend structure 130 is
formed, the exterior sides thereof are free of polishing
abrasions, thereby minimizing the diffusion of laser energy
therethrough and directing an optimum amount of such energy
from fiber core 38 through terminus 142 of tip 134. While
end structure 130 will to a degree transmit laser energy
through side surface 140 thereof when side 140 encounters
tissue, nevertheless, the degree of such laser energy
transmission through side 140 is relatively small compared
to that observed through side 138. Thus, cutting strokes
with end structure 130 are best made utilizing bend

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portion 132, if made in a direction backwards along longitudinal axis Y-Y of optical fiber 38.

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Where fiber core 38 is approximately 600 microns in diameter, the diameter D of terminus 142 will be in the range of approximately 10 microns to approximately 300 microns, depending upon the extent of focusing required in tip 134. The length L_2 of tip 134 from first end 136 thereof to terminus 142 is typically in the range of approximately 1.5 millimeters to approximately 7 millimeters. The length M of fiber core 38 utilized in creating bend portion 132 ranges from approximately 0.5 millimeters to approximately 1.5 millimeters. If sides 138 and 140 of tip 134 are projected in a direction away from fiber core 38 to intersect at a point Q, an apex angle A_2 is defined having a vertex at point P and sides coincident with sides 138, 140. In tip 134 the measure of apex angle A_2 is in the range of about 4° to about 45° , or more preferably in the range of about 9° to about 20° .

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This relative configuration is, however, subject to variation as evidenced in Figure 9 by the appearance of a second embodiment of an end structure 150 for probe 10 shown in Figure 1. There, it will be appreciated that the measure of bend angle B_1 is relatively less than the measure of bend angle B shown in Figure 8. End structure 150 comprises a bend portion 152 and a tip 154 located on the distal end thereof. The length L_3 of tip 154 is

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substantially greater than that of tip 134, and terminus 155 at the end of tip 154 is a flat surface disposed normal to the longitudinal axis Z_1-Z_1 of tip 154 having a diameter D_3 less than the diameter D_2 of terminus 142 in Figure 8. Tip 154 has an apex angle A_3 that is less than the corresponding dimension in Figure 8.

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Shown in Figure 10 is a third embodiment of an end structure 160 embodying teachings of the present invention capable of focusing laser energy from fiber core 38 in a direction off-set from longitudinal axis Y_2-Y_2 thereof. The bend angle B_2 at which this can be effected is more severe in Figure 10 than in either of Figures 8 or 9 ranging upwardly to about 90° . As seen in Figure 10, end structure 160 comprises a bend portion 162 and a tip 164 on the distal end thereof having a longitudinal axis Z_3-Z_3 and an apex angle A_4 .

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Figure 11 communicates some sense of the relative transmission capacity of an off-axis end structure, according to the present invention. There appears a curve of transmission efficiency plotted on a graph against the measure of the bend angle associated therewith. Conventionally in straight laser probes, an 80% transmission efficiency is considered in the prior art to be a normal range of transmission. As can be seen by the graphs shown in Figure 11, bend angle measures from approximately 0° to approximately 25° satisfy this

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criteria, despite the bending of laser energy direction
achieved in the process. At a reduced transmission
5 percentage of 75% to 80%, the range of the measure of the
bend angle involved can be as high as approximately 50°. Ultimately, however, it is considered to be within the
scope of the present invention when bend angles B are
10 employed ranging upwardly to approximately 90°. The use of
tips with even larger bend angles is conceivable, although
drops in transmission efficiency can be expected above
about 90°.

15 Figures 12A-12G are a series of illustrations
depicting the steps for making an end structure for an
optical waveguide, such as those shown in Figures 8-10.
Initially, Figure 12A shows an end 70 of optical fiber
20 composite 12 dimensioned suitably for use in medical laser
procedures and constructed in concentric layered fashion as
illustrated in and described above in relation to Figures 2
and 3. To produce an inventive end structure for optical
25 fiber composite 12, reinforcing jacket 42 on the exterior
thereof is removed to reveal the layer of hard cladding 40
thereunder as shown in Figure 12B. Thereafter,
30 substantially all of hard cladding 40 thereby exposed is
removed by precleaning to reveal a first portion 72 of
optical fiber core 38 therewithin. A first portion 72 is
located intermediate and adjacent to a second portion 74
35 and a third portion 76 at end 70 of fiber core 38.

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Precleaning may be effected by exposing the portion of cladding 40 overlying first, second, and third portions 72, 74, 76, respectively, to a flame, by mechanical stripping, or by washing in an acetone bath followed by drying.

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A force F_3 shown schematically in Figure 12C is applied to third portion 76 in a manner that tends to bend first portion 72. Thereafter, heat H is applied to first portion 72 until first portion 72 is rendered molten.

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The step of applying heat to first portion 72 can be accomplished by exposing first portion 72 to an electric arc. As discussed above, it is preferable that in creating an electric arc for this purpose the equipment involved produce, not a focused electric arc, but one having a broad width relative to the length of first portion 72. In this manner, a substantial length, rather than a focused point of fiber core 38 becomes heated. Heating can occur in other means described above.

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Next, a tip is formed from first portion 76 by which to narrowly focus laser energy from a medical laser. Initially a first section 166 of the length of third portion 76 is heated to render first section 166 molten. First section 166 is located intermediate and adjacent to second section 168 and third section 170 adjacent to first portion 172 of fiber core 38. A force F_4 shown schematically in Figure 12D is then applied to second

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section 68 parallel to the longitudinal axis of third
portion 176 to draw first section 166 into an hourglass
5 shape 171 shown in Figure 12E. Thereafter, the hourglass
shape is scored at point 172, broken thereat, and polished
in order to produce a terminus 174 that is both normal to
the plane defined by the event version of first
10 portion 172, while being parallel to the longitudinal axis
 Y_3-Y_3 of fiber core 38.

The effectiveness of the off-axis end structure shown
in Figures 8-9 in diverting laser energy in an off-axis
15 direction while avoiding the build-up of heat has been
confirmed by direct testing, which is reported below.

Example 4. An end structure such as that shown in
Figures 8-10 having a bend angle having a measure of
20 approximately 45° was tested to determine the percent of
laser energy transmitted therethrough into water. Each tip
was subjected to a maximum power of 100 watts for a single
25 exposure for the time indicated and was then inspected for
any adverse effects, such as darkening, chipping, or
deformation due to heat. The following test results were
observed.

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TABLE IV

5	Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
10	1	70	20	1	None
	2	77	20	1	None
	3	72	20	1	None
	4	74	20	1	None
	5	71	20	1	None
	6	76	20	1	None
15	7	77	20	1	None
	8	79	20	1	None
	9	75	20	1	None
	10	75	20	1	None

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TABLE IV
(continued)

5	Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
	11	78	20	1	None
	12	79	20	1	None
10	13	76	20	1	None
	14	78	20	1	None
	15	77	20	1	None
	16	78	20	1	None
15	17	76	20	1	None
	18	77	20	1	None
	19	78	20	1	None
20	20	78	20	1	None
	AVERAGE: 76.05%				

Mean Transmission Percent in Water: 76%

Power Source: Quantronix 118 model YAG Laser Serial
No. 688.

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Measurement: Laserguide Model 90-2030.

First, it is noteworthy that the mean transmission
percentage is much improved in relation to prior art
30 devices for focusing laser energy laterally of the tip of
a contact laser probe. Secondly, in such prior art
devices, substantial quantities of laser energy are
35 dissipated as heat, which would otherwise be expected under

the circumstances in which the above test was conducted to result in tip destruction.

Example 5. Subsequently, an end structure was complete by having a tip of frustoconical configuration and being constructed according to the teachings of the present invention and having a bend angle of approximately 30° was tested for percent power transmission in water and subjected to a maximum power test at 100 watts in a single test under the conditions listed. The results observed appear below:

TABLE V

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	80	20	1	None
2	84	20	1	None
3	80	20	1	None
4	82	20	1	None
5	81	20	1	None
6	80	20	1	None
7	81	20	1	None
8	83	20	1	None
9	82	20	1	None
10	82	20	1	None

(continued on next page)

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TABLE V
(continued)

5	Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
	11	81	20	1	None
	12	81	20	1	None
10	13	83	20	1	None
	14	82	20	1	None
	15	81	20	1	None
	16	83	20	1	None
15	17	80	20	1	None
	18	82	20	1	None
	19	81	20	1	None
20	20	82	20	1	None
	AVERAGE: 81.55%				

Mean Transmission Percent in Water: 82%

Power Source: Quantronix 118 YAG Laser Serial No. 688

25 Measurement: Laserguide Model 2030, Serial No. 002

30 Once again, in contrast to composite prior art devices in which a tip and a fiber core having different refractive indices are used in combination, the inventive tips for which test data is recorded above had an advantageously high mean transmission percentage in water of 82%. Literally no visually detectable evidence of heat damage

35 was observed.

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Thus, it can be seen that the off-axis embodiment of the inventive contact laser probe tip permits surgery to be performed orthoscopically on the walls of bodily passageways through which the laser probe is advanced to reach the surgery site. The risks associated with stray laser energy causing potential injury to healthy portions of the bodily passageway, or of damage thereto due to heat, are reduced over known devices. The simplicity and reliability of the equipment is also enhanced.

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Figure 13 illustrates yet another embodiment of an end structure 180 embodying additional teachings of the present invention in order to deliver laser energy from a medical laser to tissue to be treated according to a medical procedure while maintaining high transmission efficiency. In contrast to the tapered axially aligned tips 20 and 60 of Figures 2 and 3, respectively, and the off-axis tapered tips 130, 150, and 160 of Figures 8, 9, and 10, respectively, end structure 180 does not focus laser energy into an intense, localized pattern. Instead, end structure 180 transmits laser energy from optical fiber 12 onto a large surface area of tissue. Having this capacity, end structure 180 is ideally suited for rapidly vaporizing large volumes of tissue with which it is brought into contact. Each structure 180 has additionally been found to be effective in producing homeostasis in blood vessels severed in the process.

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In common, however, with the earlier described tapered laser probe tips and end structures, end structure 180 is disposed at the output end 182 of fiber core 38 and is integrally formed therewith from the same optically transmissive material. Ideally that optically transmissive material has an index of refraction similar to that of the tissue to be treated utilizing end structure 180. Materials which have functioned satisfactorily in this role include, quartz, silica, and certain thermoplastic materials. Typically, fiber core 38 is surrounded by a flexible jacket of hard cladding 40 which terminates short of output end 182 of fiber core 38. Exterior to hard cladding 40 is reinforcing jacket 42.

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Structurally, end structure 180 comprises a lens portion 184 which is disposed at output end 182 of fiber core 38 in a concentric relationship with the longitudinal axis Y_3-Y_3 thereof. As illustrated in the embodiment shown in Figure 13, lens portion 184 takes on an orbicular or spherical shape having a surface 186 and a diameter E_1 greater than the diameter D_2 of fiber core 38. End structure 180 also comprises, however, a transition portion 188 having a surface 190 which smoothly connects the surface 186 of lens portion 184 with the exterior of fiber core 38. Due to the manner in which end structure 180 is fabricated from the material of fiber core 38, the surface 186 of lens portion 184 and the surface 190 of transition

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portion 188 are free of scratches and polishing abrasions
which would give rise to the transmission of laser energy
5 through those surfaces and the generation of unwanted heat
thereat. In this manner, the physical nature of end
structure 180 is specifically designed to transmit laser
energy directly to the tissue at a surgical site while
10 maintaining high transmission efficiency and avoiding the
production of troublesome heat.

Typically, depending upon the size of the optical
fiber 38 utilized, the diameter E_1 of lens portion 84 is in
15 the range from about 0.3 millimeters to about 5.0
millimeters for fiber cores 38 having diameters D_2 in the
range from about 1.9 millimeters to about 4.5 millimeters,
respectively. More narrowly, however, the diameter E_1 of
20 lens portion 184 is in the range from about 0.6 millimeters
to about 3.0 millimeters where the diameter D_2 of fiber core
38 is in the range from about 0.4 millimeters to about 3.0
millimeters, respectively,. More preferably therewithin
lens portion 184 has a diameter E_1 in the range about 0.8
millimeters to about 2.5 millimeters, where the diameter D_2
of fiber core 38 is in the range from about 0.6 millimeters
30 to about 2.0 millimeters. For example, where the diameter
 D_2 of fiber core 38 is about 1.0 millimeters, an appropriate
diameter E_1 for lens portion 184 would be about 1.2
millimeters. With a smaller fiber core 38 as, for example,
35 a fiber core 38 having a diameter D_2 that is about 0.6

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millimeters, the anticipated appropriate diameter E_1 of lens portion 184 would be about 0.8 millimeters.

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The advantageous optical features of end structure 180 will be explored in relation to Figures 14 and 15 taken together.

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According to one aspect of the present invention, end structure 180 comprises a means for focusing a portion of the laser energy delivered from output end 182 of fiber core 138 through a fast focal point align with the longitudinal axis of $Y_3 - Y_3$ of fiber core 38 at output end 182 thereof. As used herein and in the appended claims, this modality of laser energy transmission from end structure 180 will be referred to as the carrier mode of laser energy transmission, and the portion of the laser energy focused through a fast focal point will be referred to as a "second portion" of that energy.

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As shown in Figure 14, a plurality of rays W_1 , W_2 , W_3 , W_4 , and W_5 of laser energy are delivered from output end 182 of optical fiber 38 into transition portion 188 and therethrough into lens portion 184. These rays of laser energy are possessed of various degrees of alignment with longitudinal axis $Y_3 - Y_3$ of fiber core 38. Some of the rays of laser energy, such as the rays W_2 and W_3 of laser energy, are of a very low order mode, traveling closely parallel to longitudinal axis $Y_3 - Y_3$. Absent any severe kinking in optical fiber 12, it can be expected that low order rays of

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laser energy, such as laser energy rays W_2 and W_3 , will continue to maintain a low order mode throughout the length of the fiber and during the passage across lens portion 184 of end structure 180.

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Low order rays of laser energy, such as laser energy rays W_2 and W_3 impact the surface 186 of lens portion 184 remote from fiber core 38 in a circular region having in the view of Figure 14 extreme points J and K. The surface 186 of lens portion 184 located between points J and K then functions as a positive lens to focus such low order laser energy rays through a fast focal point X. The second portion of the laser energy thus delivered through fast focal point X accordingly corresponds to low order rays of laser energy, such as rays W_2 and W_3 . Fast focal point X will fall on longitudinal axis Y_3 - Y_3 , if end structure 180 between points J and K is symmetric about that longitudinal axis. Minor asymmetrical irregularities in end structure 180 are not, however, considered to depart from the spirit of the present invention, in that it is not the positioning of fast focal X that gives end structure 180 its utility. While the existence of a fast focal X is a physical parameter useful in describing end structure 180, it is another aspect of the present invention which gives end structure 180 its major utility for rapidly vaporizing large volumes of tissue during a medical procedure. Thus, according to yet another aspect of the present

1 invention, end structure 180 comprises means for internally
star-reflecting in a region of multi-directional laser
5 energy a portion of the laser energy delivered from output
end 132 of fiber core 38. As used herein and in the
appended claims, the portion of the laser energy thus
internally reflected in the region of multi-dimensional
10 laser energy in lens portion 184 corresponds to low order
rays of energy delivered from output end 182 of fiber core
38. Again, as seen in Figure 14 a number of high order
rays of laser energy W_1 , W_4 , and W_5 are delivered from output
15 end 182 of fiber core 38 into end structure 180. These
high order rays of laser energy do not normally impact the
surface 186 of lens portion 84 between points J and K so as
to be focused through fast focal point X. Instead, high
20 order rays of laser energy, such as laser energy rays W_1 ,
 W_4 , and W_5 are initially reflected internally off of the
abrasion-free surfaces 186 of lens portion 184 and 190 of
transition portion 188. These high order rays of laser
25 energy continue thereafter to be reflected internally and
successively about lens portion 184 in a star-reflecting
pattern which develops within lens portion 184 a region of
30 multi-directional laser energy which is not normally
transmitted therefrom in any substantial degree. Some of
the star-reflecting, multi-directional laser energy will in
due course impact the surface 186 of lens portion 184
35 between points J and K at an appropriate angle to become

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focused with high order rays, such as laser ray W_3 , through
fast focal point X. Other individual rays of the star-
5 reflecting, multi-directional laser energy in lens portion
184 will occasionally escape from end structure 180
backwards into output end 182 of fiber core 38.
Nevertheless, these losses of the star-reflecting, multi-
10 directional laser energy are minor when compared with the
energy contained in high order rays of laser energy
arriving on a continuing basis through transition portion
188 from output end 182 of fiber core 38.

15 Thus, while transmitting a portion of the laser energy
delivered from output end 182 of fiber core 38 in a carrier
mode of transmission, another portion of the laser energy
delivered from output end 182 of fiber core 38 is
20 internally star-reflected to form in lens portion 84 a
region of multi-directional laser energy having as its
boundary the surface 186 of lens portion 184. A typical
pattern of plural internal star-reflections is shown in
25 Figure 14 for laser energy ray W_1 . The path of travel of
the successive reflections of other high order rays of
laser energy, such as rays W_4 or W_5 , has for the sake of
30 clarity been omitted. Nevertheless, a similar series of
almost endless internal reflections will occur in each
instance for the high order rays illustrated and for each
successive high order ray of laser energy delivered from
35 output end 182 of fiber core 38. The containment of the

1 multi-directional laser energy in lens portions 184 is
dependent upon two factors: the absence of abrasions on
5 surface 186 of lens portion 184, and the presence on
surface 186 of lens portion 184 of no material with an
index of refraction closely matched to the index of
refraction of the optically transmissive material of which
10 end structure 180 is comprised. When no such index
matching material is in contact with surface 186 of lens
portion 184, end structure 180 operates in the carrier mode
of transmission passing but a portion of the laser energy
15 emerging from output end 182 of fiber core 38 by focusing
such laser energy through fast focal point X.

Nevertheless, as illustrated in Figure 15, end
20 structure 180, which has already been identified as
functioning as a means for internally star-reflecting
another portion of the laser energy delivered from output
end 182 of fiber core 38, also functions as a means for
25 selectively directing that multi-directional laser energy
in lens portion 184 through surface 186 thereof at such
portions of surface 186 as contact an organic tissue or
fluid exhibiting a close refractive index match with fiber
30 core 38.

As shown in Figure 15, end structure 180 has been
advanced into contact with an area of tissue 192, whereby
tissue 192 contacts surface 186 of lens portion 184 at the
35 arcs thereof disposed between points M and N and between

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points P and Q. The index of refraction for tissue 192 is similar to that for fiber core 138 and end portion 180.

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Under such circumstances, the second portion of the laser energy delivered from fiber core 38 that is internally star-reflected within lens portion 184 no longer continues to be reflected in this manner whenever that energy

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encounters surface 186 of lens portion 184 between points M and N or between points P and Q. Instead, the multi-directional laser energy in lens portion 84 is transmitted into tissue 192 wherever that tissue contacts surface 186.

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Thus, as the multi-directional laser energy in lens portion 184 encounters surface 186 between points M and N, rather than being reflected therefrom, it is directed through

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surface 186 into tissue 192. In Figure 15, this component of the multi-directional laser energy in lens portion 184 has been designated by W_{MN} . Correspondingly, a component of

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the multi-directional laser energy in lens portion 184 is directed into tissue 192 through surface 186 between points P and Q, and has been designated in Figure 15 as W_{PQ} . The laser energy W_{MN} and W_{PQ} directed into tissue 192 is not

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focused into a narrow beam, but rather impacts a broad portion of the surface of tissue 192 and is ideally suited for rapid vaporization of substantial volumes of such tissue.

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The portions of surface 186 of lens portion 184 which are not contacted by tissue 192, however, continue to

1 internally star-reflect high order rays of laser energy.
In Figure 15 this would include, for example, the portion
5 of surface 186 between points N and P and the portions of
surface 186 between fiber core 38 and points M and Q,
respectively. There, high order laser energy rays continue
to be internally reflected into the region of multi-
10 directional laser energy bounded by surface 186. Thus, by
way of example, laser energy ray W_1 is shown internally
star-reflecting from surface 186 between points N and P
thereon as well as from surface 186 between point Q and
15 fiber core 38.

It should be noted that while an avalanche mode of
transmission is shown occurring in Figure 15, the carrier
mode of transmission of low order rays of laser energy
20 continues, directing such rays as impact surface 186
between points J and K through fast focus X. Should tissue
192 contact surface 186 between points J and K thereon, the
laser energy normally transmitted therethrough in the
25 carrier mode of transmission would then enter tissue 192
for the purpose of vaporizing same. Such a situation,
while not illustrated explicitly in Figure 15 can easily be
30 visualized.

Figure 16 illustrates yet another embodiment of an end
structure 200 embodying teachings of the present invention,
including those discussed already in relation to end
35 structure 180 shown in Figure 13. End structure 200 is

1 integrally formed on output end 182 of fiber core 38 so as
to have sides free of scratches and polishing abrasions,
5 and thereby to be capable of transmitting laser energy
delivered from output end 182 of fiber core 38 while
maintaining high transmission efficiency. End structure
200 comprises a generally cylindrical bend portion 202
10 having a proximal end 204 coextensive with output end 182
of fiber core 38 and a distal end 206 opposite therefrom.
The longitudinal axis Z_3 - Z_3 of bend portion 202 at distal
end 204 thereof diverts from the longitudinal axis Y_4 - Y_4 of
15 output end 82 of fiber core 38 at predetermined bend angle
 B_3 . Due to the same optical limitations discussed in
relation to the off-axis end structures 130, 150, and 160
illustrated in Figures 8, 9, and 10, respectively, bend
20 angle B_3 can assume a range from about 0° to about 90° .
More particularly, however, the range of bend angle B_3 is
from about 15° to about 60° or, more narrowly, from about
25 30° to about 45° .

End structure 200 also comprises a lens portion 208
disposed at distal end 206 of bend portion 202
concentrically with longitudinal axis Z_3 - Z_3 thereof. A
30 transition portion 210 having surfaces 212 smoothly
connects the surface 214 of lens portion 208 to bend
portion 202. As in end structure 180 shown in Figure 13,
lens portion 208 is orbicular or spherical, having a
35 diameter E_2 that is greater than the diameter D_3 of fiber

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core 38 and bend portion 202. The size of the diameter E_2
of lens portion 208 varies primarily according to the
5 diameter D_3 of fiber core 38 in the same range as stated in
relation to the diameter E_1 of lens portion 184 illustrated
in Figure 13. The length M_1 of bend portion 202 is found
generally in the range of from about 0.5 millimeters to
10 about 1.5 millimeters.

In operation, as discussed previously in relation to
the embodiments illustrated in Figures 8, 9, and 10, laser
energy from fiber core 38 is redirected by bend portion 202
15 in order to enter transition portion 210 and lens portion
208 at an angle which generally diverges from longitudinal
axis Y_4-Y_4 of fiber core 38 by the predetermined bend angle
 B_3 . End structure 200 functions as a means for focusing a
20 portion of the laser energy from fiber core 38. As in the
case of end structure 180 of Figure 13, low order rays of
laser energy are transmitted through the tip 216 of lens
portion 208 and focused through a fast focal point aligned
25 with longitudinal axis Z_3-Z_3 of distal end 206 of bend
portion 202. Thus, a second portion of the laser energy
delivered through output end 182 of fiber core 38
30 corresponding to low order rays of laser energy is
transmitted through end structure 200 in a carrier mode of
transmission. In the manner already discussed in relation
to Figures 14 and 15, however, end structure 200 also
35 functions as a means for internally star-reflecting in a

1 region of multi-directional laser energy a first portion of
the laser energy delivered from fiber core 38 and for
5 selectively directing that multi-directional laser energy
in an avalanche mode of transmission through the boundary
of that region at such portions thereof as contact a
biological tissue or fluid having an index of refraction
10 matching that of fiber core 38. Once laser energy from
fiber core 38 has been redirected by bend portion 202 of
end structure 200, the mechanism by which this occurs is
substantially identical to that already discussed in detail
15 in relation to end structure 180 in Figure 13.

End structure 200 has been found to be particularly
useful in directing laser energy onto tissue located to the
20 side of a laser probe as, for example, on the wall of a
body passageway. In contrast to the effect obtained by the
inventive embodiments illustrated in Figures 8, 9, and 10,
however, end structure 200 does not focus that laser energy
25 into a narrow beam for the purpose of incising the tissue,
but rather applies laser energy to that tissue in a large
area contacted by the laser tip. The tip is thus ideally
suited to vaporizing large volumes of tissue. Desirable
30 hemostasis effects also accrue when end structure 200 is
utilized.

Figures 17A through 17E illustrate the manner in which
both end structure 180 and end structure 200 can be
35 fabricated from an optical fiber 12. Initially,

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reinforcing jacket 42 and hard cladding 40 are removed from a section of fiber core 38 immediately adjacent to end 70 thereof. The outer surface of fiber core 38 is thereafter cleaned, resulting in the structure illustrated in Figure 17A. The steps of the procedure to this point parallel those discussed already in relation to Figures 7A-7C.

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Thereafter, end 70 of fiber core 38 is oriented downwardly in a generally vertical direction at an inclination angle C to a vertical axis $V-V$. With fiber core 38 rotating about the longitudinal axis Y_5-Y_5 , as shown by arrow R , a first portion 220 adjacent to end 70 is heated by the application of heat H thereto. This can occur in any of the manners of heat application discussed previously in relation to the application of heat H as, for example, in relation to Figure 7D. Heat H is applied to first portion 220 for sufficient time to permit first portion 220 to assume a molten state. Thereafter, the surface tension on the molten form of first portion 220 causes first portion 220 to assume the bulbous shape 222 shown in Figure 17C as having smoothly flaring sides 224 and a diameter E_3 that is greater than the diameter D_4 of fiber core 38. Bulbous shape 222 is then cooled resulting in an axially aligned orbicular end structure 226 equivalent to end structure 180 shown in Figure 13.

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Further processing is required in order to produce an off-axis orbicular end structure, such as end structure 200

1 shown in Figure 16. As illustrated in Figure 17D, heat H
is applied to a second portion 228 of the length of fiber
5 core 38 that is located intermediate and adjacent to end
structure 226 and a third portion 230 of fiber core 38.
Simultaneously, a force F_5 directed normal to longitudinal
axis Y_5 - Y_5 of fiber core 38 is applied to end structure 226.
10 Much in the manner already discussed in relation to Figure
12C, the heat H applied to second portion 228 renders
second portion 228 molten, so that force F_5 is able to bend
second portion 228 out of alignment with longitudinal axis
15 Y_5 - Y_5 of fiber core 38 into the bent position shown in
Figure 17E. Cooling produces a device corresponding to end
structure 200 shown in Figure 16.

20 The end structure produced in this manner is both
integral with fiber core 38 and has surfaces free of
scratches and polishing abrasions. It is, therefore,
capable of transmitting laser energy delivered from fiber
25 core 38 in a highly efficient manner, without generating
unwanted heat. In the case of the orbicular or spherical
end structure created in this manner, the vaporization of
large volumes of tissue by direct contact therewith is
30 particularly facilitated, and the control of blood flow
from severed tissues is greatly enhanced. Axially aligned
and axially off-set configurations of the orbicular tip
have specific special applications.

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The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

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What is claimed is:

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1. An optical waveguide for use in a medical procedure for the transmission of laser energy from a medical laser to tissue to be treated according to the medical procedure, said waveguide comprising:

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(a) a fiber core of optically transmissive material having an input end for receiving the laser energy and an output end remote therefrom for delivering the laser energy to the tissue; and

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(b) tip means formed of said optically transmissive material integrally with said fiber core for directing laser energy from said output end of said fiber core and for delivering said laser energy with high transmission efficiency to selected portions of the tissue.

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2. An optical waveguide as recited in Claim 1, wherein said tip means comprises an end structure on said output end of said fiber core, said end structure having surfaces free of polishing abrasions.

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3. An optical waveguide as recited in Claim 2, wherein said end structure is formed from a molten portion of said fiber core.

5

4. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for internally star-reflecting a first portion of the laser energy delivered from said output end of said fiber core in an avalanche mode of transmission and for directing said multi-directional laser energy through the boundary of said region of multi-directional energy at such portions of said boundary as contact the tissue, said first portion of the laser energy corresponding to high order rays of laser energy delivered from said output and of said fiber core.

15

5. An optical waveguide as recited in Claim 4, wherein said region of multi-directional laser energy is orbicular.

20

6. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting in a carrier mode of transmission focuses a second portion of the laser energy delivered from said output end of said fiber core through a fast focal point aligned with the longitudinal axis of the fiber core at the output end thereof, said second portion of the laser energy corresponding to low order rays of laser energy delivered from said output end of said fiber core.

25

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7. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting comprises a positive lens.

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8. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting comprises an end structure on said output end of said fiber core, having surfaces defining the boundary of said region of multi-directional laser energy, said surfaces of said end structure being free of polishing abrasions.

5

9. An optical waveguide as recited in either of Claims 8 or 2, wherein said end structure comprises:

10

(a) a lens portion disposed at said output end of said fiber core concentrically with the longitudinal axis thereof; and

15

(b) a transition portion smoothly connecting the surface of said lens portion to the sides of said fiber core.

10. An optical waveguide as recited in either of Claims 8 or 2, wherein said end structure comprises:

20

(a) a generally cylindrical bend portion having a proximal end radially coextensive with said output end of said fiber core and a distal end opposite therefrom, the longitudinal axis of said bend portion at said distal end thereof diverting from the longitudinal axis of said output end of said fiber core at a predetermined bend angle;

25

(b) a lens portion disposed at said distal end of said bend portion concentrically with the longitudinal axis thereof; and

30

(c) a transition portion smoothly connecting the surface of said lens portion to the sides of said distal end of said bend portion.

11. An optical waveguide as recited in either of Claims 9 or 10, wherein said lens portion is orbicular.

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12. An optical waveguide as recited in either of Claims 9 or 10, wherein the diameter of said lens portion is greater than the diameter said distal end of said bend portion.

13. An optical waveguide as recited in Claim 12, wherein the diameter of said lens portion is in the range of about 0.3 millimeters to about 5.0 millimeters.

14. An optical waveguide as recited in Claim 13, wherein the diameter of said lens portion is in the range of about 0.6 millimeters to about 3.0 millimeters.

15

15. An optical waveguide as recited in Claim 14, wherein the diameter of said lens portion is in the range of about 0.8 millimeters to about 2.5 millimeters.

20

16. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for focusing a second portion of the laser energy delivered from said output end of said laser core in a carrier mode of transmission through a fast focal point aligned with the longitudinal axis of the fiber core at said output end thereof, said second portion of the laser energy corresponding to low order rays of laser energy from said output end of said fiber core, and said means for focusing being formed of said optically transmissive material integrally with said fiber core at said output end thereof.

30

17. An optical waveguide as recited in Claim 16, wherein said means for focussing comprises a positive lens.

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18. An optical waveguide as recited in Claim 17,
wherein said means for focusing comprises an end structure
on said output end of said fiber core, having surfaces free
5 of polishing abrasions.

10

19. An optical waveguide as recited in Claim 18,
wherein a first portion of the laser energy from said
output end of said fiber core is transmitted in an
avalanche mode of transmission through the surface of said
lens portion at such portions thereof as contact the
tissue, said first portion of the laser energy
corresponding to high order rays of laser energy from said
output end of said fiber core.

15

20. An optical waveguide as recited in Claim 1,
wherein said tip means comprises means for narrowly
focusing the laser energy from said output end of said
fiber core onto portions of the tissue offset laterally
20 from the longitudinal axis of said fiber core at said
output end thereof.

25

21. An optical waveguide as recited in Claim 20,
wherein said means for narrowly focusing comprises an end
structure on said output end of said fiber core having side
surfaces free of polishing abrasions, thereby minimizing
the diffusion of laser energy through said side surfaces of
said end structure.

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22. An optical waveguide as recited in either of Claims 2 or 21, wherein said end structure comprises:

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(a) a generally cylindrical bend portion having a proximal end radially coextensive with said output end of said fiber core and a distal end opposite therefrom, the longitudinal axis of said bend portion at said distal end thereof diverting from the longitudinal axis of said output end of said fiber core at a predetermined bend angle; and

10

(b) a tip formed on said distal end of said bend portion.

15

23. An optical waveguide as recited in either of Claims 10 or 22, wherein said predetermined bend angle at which the longitudinal axis of said bend portion at said distal end thereof diverts from the longitudinal axis of said output end of said fiber core ranges upwardly to approximately 90°.

20

24. An optical waveguide as recited in Claim 23, wherein the measure of said predetermined bend angle is in the range of about 15° to about 60°.

25

25. An optical waveguide as recited in Claim 24, wherein the measure of said predetermined bend angle is in the range of about 30° to about 45°.

30

26. An optical waveguide as recited in either of Claims 10 or 22, wherein the length of said bend portion is in the range of about 0.5 millimeters to about 1.5 millimeters.

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27. An optical waveguide as recited in Claim 22,
wherein said sides of said tip taper smoothly from a first
end adjacent said proximal end of said bend portion to a
terminus comprising a flat surface at a second end remote
therefrom.

28. An optical waveguide as recited in Claim 22,
wherein said terminus of said tip is disposed normal to the
plane of said bend portion and parallel to the longitudinal
axis of said fiber core at said output end thereof.

29. An optical waveguide as recited in Claim 22,
wherein said terminus of said tip is normal to the
longitudinal axis of said tip.

30. An optical waveguide as recited in Claim 22,
wherein said bend portion is formed from a molten portion
of said fiber core by twisting out of longitudinal
alignment portions of said fiber core on opposite sides of
said a molten portion.

31. An optical waveguide as recited in Claim 22,
wherein said tip is formed by drawing a molten portion of
said fiber core located on the side of said bend portion
opposite from said output end of said fiber core away from
said bend portion in a direction aligned with the
longitudinal axis of said bend portion at said distal end
thereof.

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32. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for narrowly focusing the laser energy from said output end of said fiber core onto portions of the tissue aligned with the longitudinal axis of said fiber core at said output end thereof.

10

33. An optical waveguide as recited in Claim 32, wherein said means for narrowly focusing comprises an end structure in the form of a tip on said output end of said fiber core having side surfaces free of polishing abrasions, thereby minimizing the diffusion of laser energy through said side surfaces of said tip.

15

34. An optical waveguide as recited in Claim 33, wherein said sides of said tip taper smoothly from a first end adjacent said fiber core to a terminus at a second end remote from said fiber.

20

35. An optical waveguide as recited in Claim 34, wherein said terminus of said tip comprises a flat surface disposed normal to the longitudinal axis of said fiber core.

25

36. An optical waveguide as recited in either of Claims 29 or 32, wherein said tip is frustoconical.

30

37. An optical waveguide as recited in Claim 36, wherein the length of said tip is in the range of about 1.5 millimeters to about 7.0 millimeters.

35

38. An optical waveguide as recited in Claim 37, wherein the length of said tip is in the range of about 1.5 millimeters to about 2.5 millimeters.

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39. An optical waveguide as recited in either of Claims 27 or 33, wherein the diameter of said terminus of said tip is in the range of about 75 microns to about 300 microns.

40. An optical waveguide as recited in Claim 39, wherein the diameter of said terminus of said tip is in the range of about 75 microns to about 125 microns.

41. An optical waveguide as recited in either of Claims 27 or 33, wherein the apex angle formed by projecting said sides of said tip to an intersection beyond the terminus thereof is in the range of about 4 degrees to about 45 degrees.

42. An optical waveguide as recited in Claim 41, wherein the apex angle formed from projecting said sides of said tip to an intersection beyond the terminus thereof is in the range of about 9 degrees to about 20 degrees.

43. An optical waveguide as recited in Claim 33, wherein said tip is rotationally symmetric.

25

44. An optical waveguide as recited in Claim 43, wherein said tip is formed by drawing a molten portion of said output end of said fiber core away from said fiber core in a direction aligned with the longitudinal axis thereof.

30

45. An optical waveguide as recited in either of Claims 8, 21, or 33, wherein said end structure is formed from a molten portion of said fiber core.

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46. An optical waveguide as recited in Claim 1,
wherein said optically transmissive material has an index
5 of refraction similar to that of the tissue.

10

47. An optical waveguide as recited in Claim 46,
wherein said optically transmissive material comprises
quartz.

15

48. An optical waveguide as recited in Claim 45,
wherein said optically transmissive material comprises
silica.

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49. An optical waveguide as recited in Claim 46,
wherein said optically transmissive material comprises a
thermoplastic material.

25

50. An optical waveguide as recited in either one of
Claims 8, 21, or 33, further comprising a flexible jacket
surrounding said fiber core, and wherein said end structure
is free of said flexible jacket.

30

51. An optical waveguide as recited in Claim 51,
further comprising a cladding about said flexible jacket
for stiffening said fiber core.

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52. An optical waveguide as recited in Claim 51,
further comprising a handle fixed to and surrounding said
cladding in the vicinity of said tip.

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53. An optical waveguide as recited in Claim 1, wherein said fiber core is comprised of a first optically transmissive solid material having an index of refraction similar to that of the tissue; and wherein said waveguide further comprises a sheath surrounding said fiber core, said sheath being comprised of a second optical transmissive solid material having an index of refraction substantially equal to said first index of refraction.

10

54. An end structure for an optical laser fiber core, said end structure being integrally formed with said fiber core so as to be radially coextensive at a first end thereof with the end of said fiber core and to have sides flaring smoothly outward from said first end to a terminus at a second end remote from said fiber core.

15

55. An end structure as recited in Claim 54, wherein the surface of said sides of said end structure are free from polishing abrasions, thereby minimizing the diffusion of laser energy through said side surfaces of said end structure.

20

56. An end structure as recited in Claim 55, wherein said end structure comprises a tip for said fiber core taking form of a generally hemispherical shape.

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57. An end structure as recited in Claim 56, wherein said terminus of said tip comprises the planar surface of said generally hemispherical shape.

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58. An end structure as recited in Claim 54, wherein said tip comprises a bulbous shape having a maximum diameter taken normal to the longitudinal axis of said fiber core that is greater than the diameter of said fiber core, the sides of said bulbous shape smoothly merging into the sides of said fiber core, and said bulbous shape terminating at the end thereof remote from said fiber core in a flat surface disposed normal to the longitudinal axis of said fiber core.

10

59. An end structure as recited in Claim 58, wherein said flat surface of said bulbous shape comprises said terminus of said tip.

15

60. An end structure as recited in Claim 54, wherein said tip is located at the input of said fiber core.

61. An end structure as recited in Claim 54, wherein said tip is located at the output end of said fiber core.

20

62. An end structure as recited in Claim 54, wherein the maximum diameter of said tip taken normal to the longitudinal axis of said fiber core is in the range of from about 600 microns to about 800 microns.

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63. A method for making a tip for an optical waveguide for use with a medical laser in a predetermined medical procedure, said method comprising the steps:

5

(a) heating a first portion of the length of a fiber core of optically transmissive material to render said first portion molten, said first portion of said fiber core being located intermediate and adjacent to second and third portions of said fiber;

10

(b) drawing said third portion of said fiber core away from said heated first portion parallel to the longitudinal axis of said fiber thereby to produce from said heated first portion, at the end thereof adjacent said second portion of said fiber core, a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from said second portion;

15

(c) cooling said shape;

20

(d) scoring said shape at a scoring point located a preselected distance along said shape from said second portion of said fiber core; and

25

(e) breaking said shape at said scoring point to form from said shape integrally with said second portion of said fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through said fiber core to said second portion thereof.

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64. A method for making a tip for the end of an optical fiber core, said method comprising the steps:

5 (a) orienting the end of the optical fiber core in a vertical direction;

(b) heating a first portion of the length of the fiber core adjacent the end thereof to render said first portion molten;

10 (c) maintaining the vertical orientation of said fiber core to permit said heated first portion thereof to assume a bulbous shape having smoothly flaring sides and a maximum diameter taken normal to the longitudinal axis of said fiber core that is greater than the diameter of said fiber;

15 (d) cooling said bulbous shape; and

(e) removing the end of said shape remote from the fiber core to produce thereat a flat surface disposed normal to the longitudinal axis of the fiber core.

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65. A method for making an end structure for the output end of an optical waveguide useable with a medical laser in a predetermined medical procedure, said method comprising the steps:

5

(a) heating a first portion of the length of a fiber core of optically transmissive material to render said first portion molten, said first portion of said fiber core being located intermediate and adjacent to second and third portions of said fiber core;

10

(b) bending said first portion of said fiber core so that the longitudinal axis of said third portion is at a predetermined angle to the longitudinal axis of said second portion;

15

(c) cooling said second portion; and

(d) forming a tip from said first portion of said fiber core for narrowly focusing laser energy from the medical laser.

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66. A method as recited in Claim 65, wherein said step of forming a tip from said third portion of said fiber core comprises the steps:

5

(a) heating a first section of the length of said third portion to render said first section molten, said first section being located intermediate and adjacent to second and third sections of said third portion, and said second section being adjacent to said first portion of said fiber core;

10

(b) drawing said third section of said third portion of said fiber core away from said heated first section parallel to the longitudinal axis of said first portion of said fiber core at the end thereof remote from said second portion of said fiber core, thereby to produce from said heated first section, at the end thereof adjacent said second section, a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from said second section; (c) cooling said shape;

15

20

(d) scoring said shape at a scoring point located a preselected distance along said shape from said second section; and

25

(e) breaking said shape at said scoring point to form from said shape integrally with said second section of said third portion of said fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through said fiber core to said third portion thereof.

30

67. A method as recited in either of Claims 63, 64 or 65, further comprising the step of polishing said tip to produce at the end thereof a terminus comprising a flat surface.

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68. A method as recited in either of Claims 63, 64 or 65, further comprising the step of polishing said tip to remove stress cracks at said scoring point.

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69. A method as recited in either of Claims 63, 64 or 65, further comprising the step of removing the reinforcing jacket about said fiber core prior to said step of heating said first portion.

10

70. A method as recited in either of Claims 63, 64 or 65, further comprising the step of precleaning said fiber core to remove cladding therefrom prior to said step of heating said first portion.

15

71. A method as recited in Claim 70, wherein said step of precleaning comprises the step of exposing the outer surface of said fiber core to a flame.

20

72. A method as recited in Claim 70, wherein said step of precleaning comprises the steps of:

(a) washing said fiber core in an acetone bath;
and

(b) drying said fiber core.

25

73. A method as recited in Claim 70, wherein said step of precleaning comprises the step of mechanically stripping cladding from said fiber core.

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74. A method for making a tip for the end of an optical fiber core, said method comprising the steps of:

5

(a) orienting the end of the optical fiber core in a generally vertical direction;

(b) rotating said end of the optical fiber core about the longitudinal axis thereof;

10

(c) heating a first portion of the length of the fiber core adjacent the end thereof to render said first portion molten;

(d) permitting said heated first portion of said fiber core to assume a bulbous shape having smoothly flaring sides and a diameter that is greater than the diameter of said fiber; and

15

(e) cooling said bulbous shape.

20

75. A method as recited in Claim 74, wherein said step of orienting comprises the step of disposing the end of the optical fiber core in a downwardly oriented direction.

25

76. A method as recited in Claim 75, wherein said end of said optical fiber core is oriented at an inclination angle to the vertical in a range from about 10° to about 15°.

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77. A method as recited in Claim 76, further comprising the steps:

5

(a) heating a second portion of the length of the fiber core to render said second portion molten, said second portion of said fiber core being located intermediate and adjacent to said first portion of said fiber core and a third portion of said fiber core;

10

(b) bending said second portion of said fiber core so that the longitudinal axis of said end thereof adjacent said first portion of said fiber core diverges at a predetermined angle from the longitudinal axis of said third portion of said fiber core; and

15

(c) cooling said second portion of said fiber core.

20

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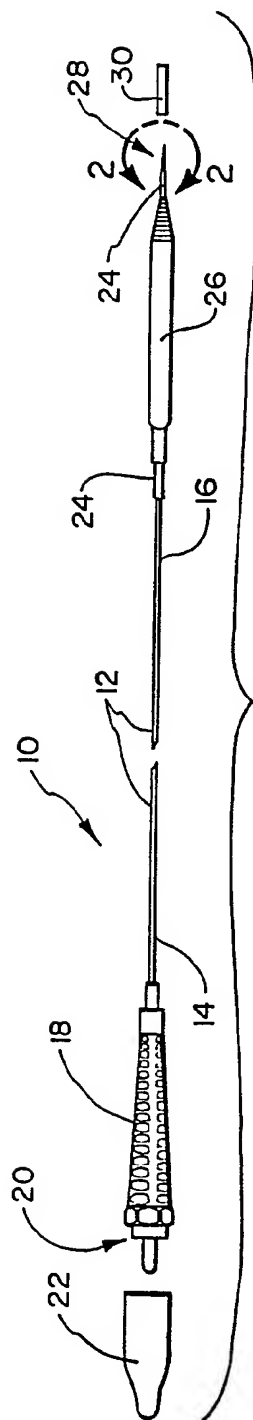


FIG. 1

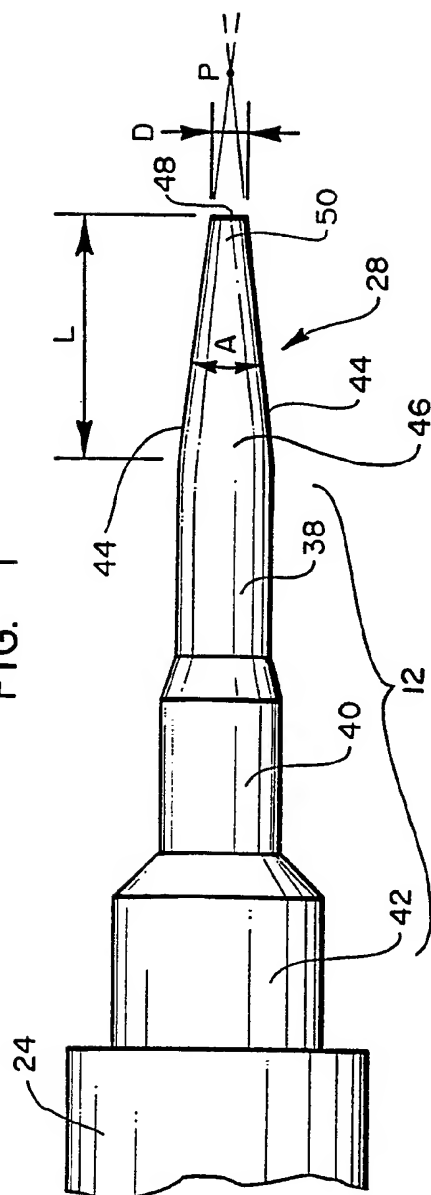


FIG. 2

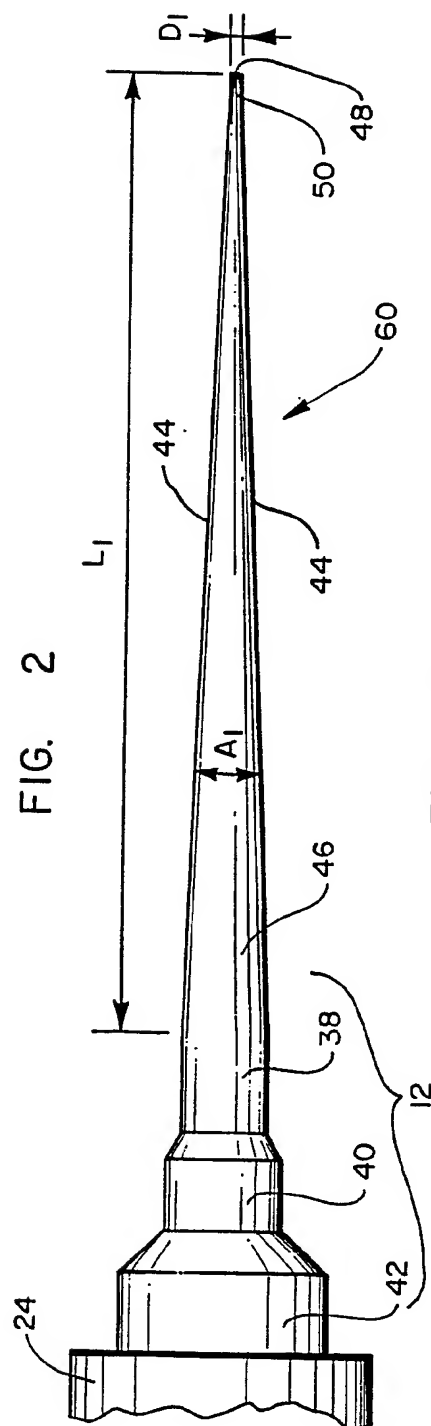
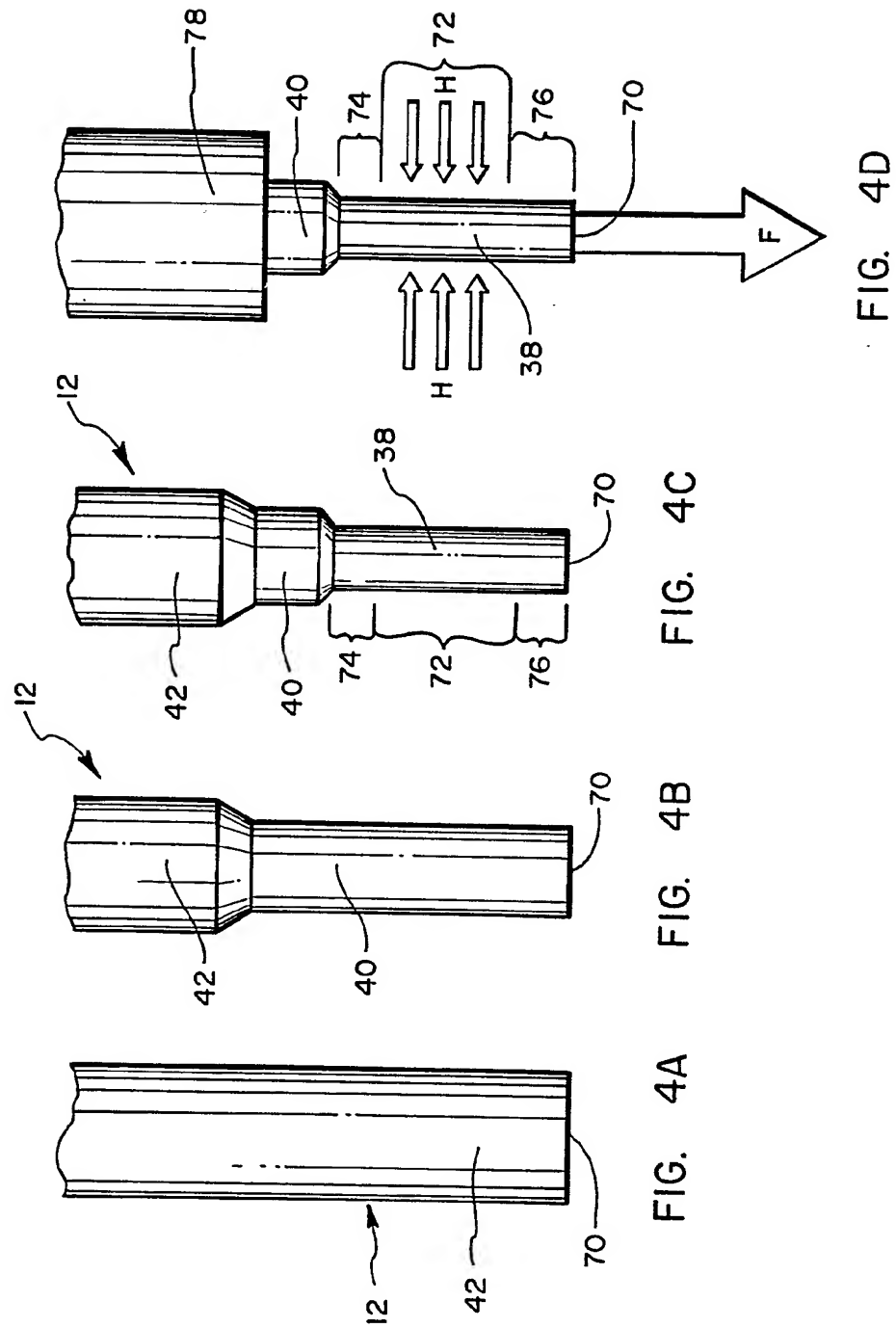


FIG. 3



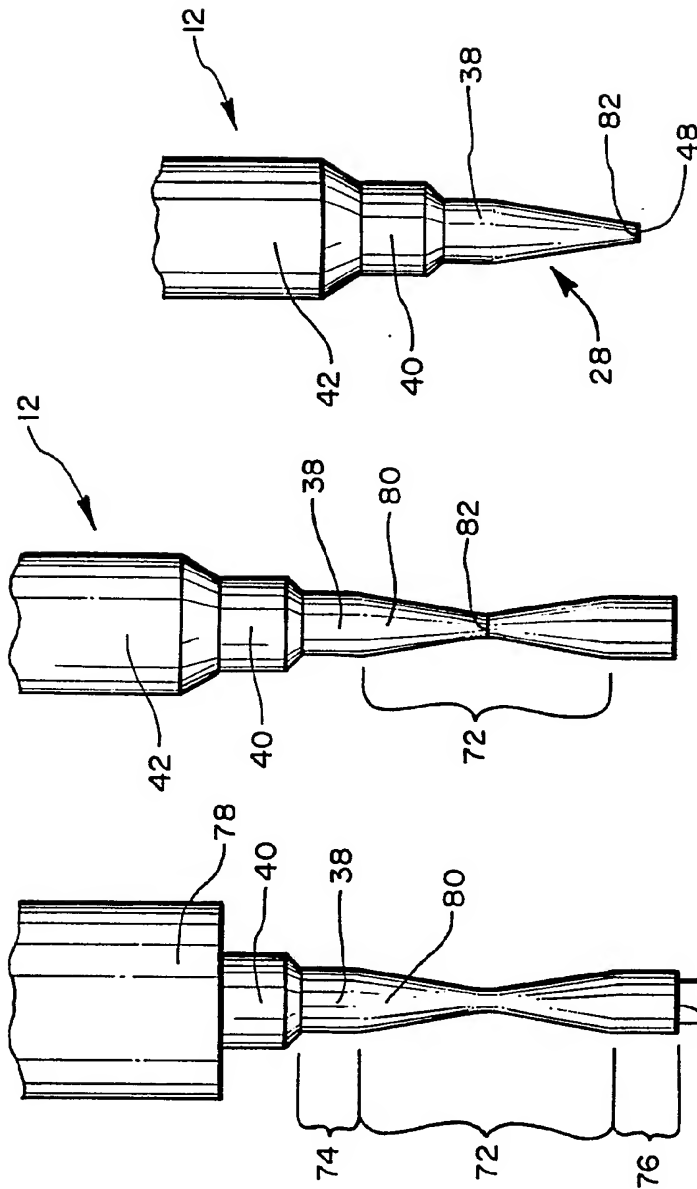
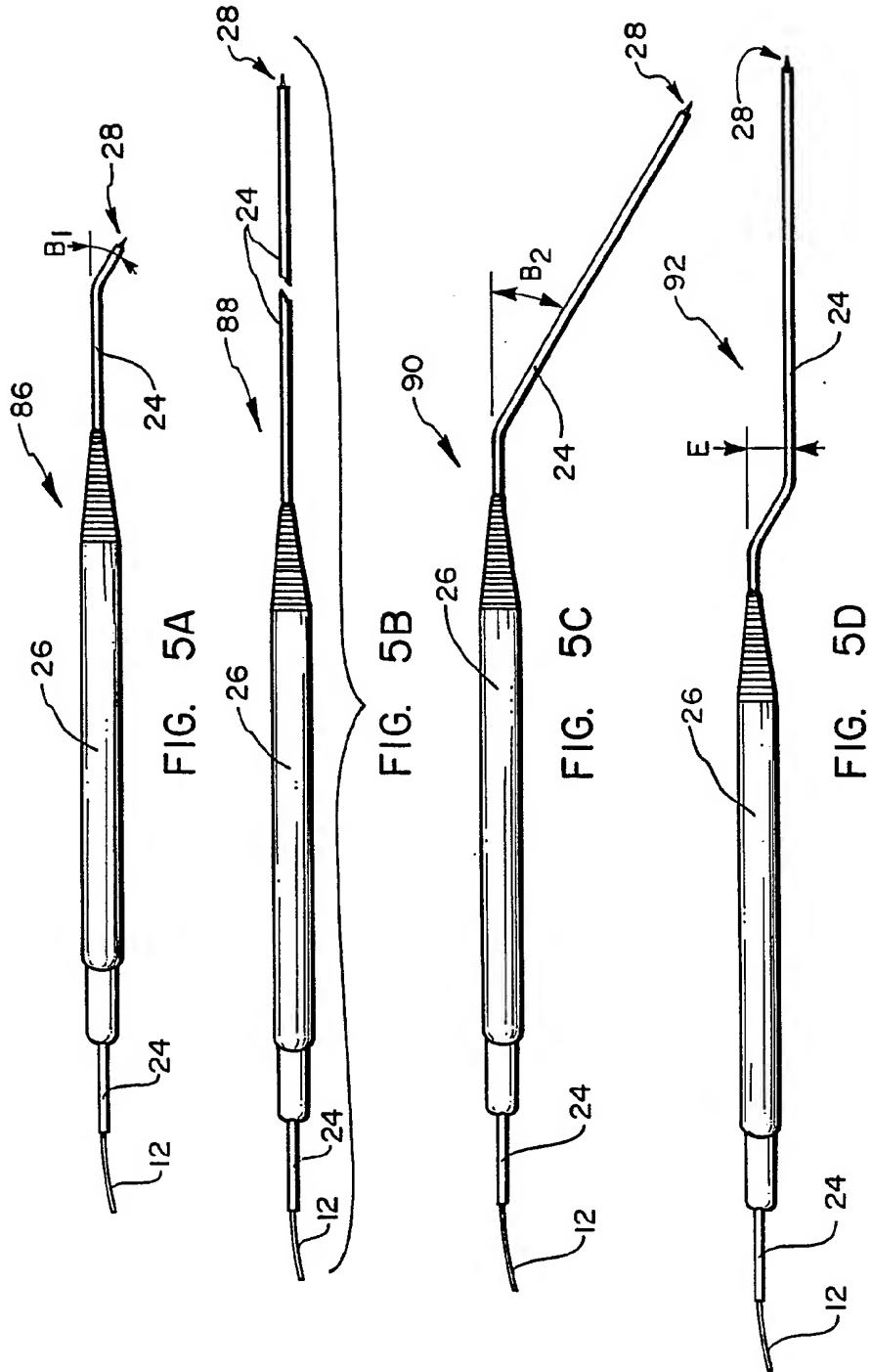


FIG. 4G

FIG. 4F

FIG. 4E



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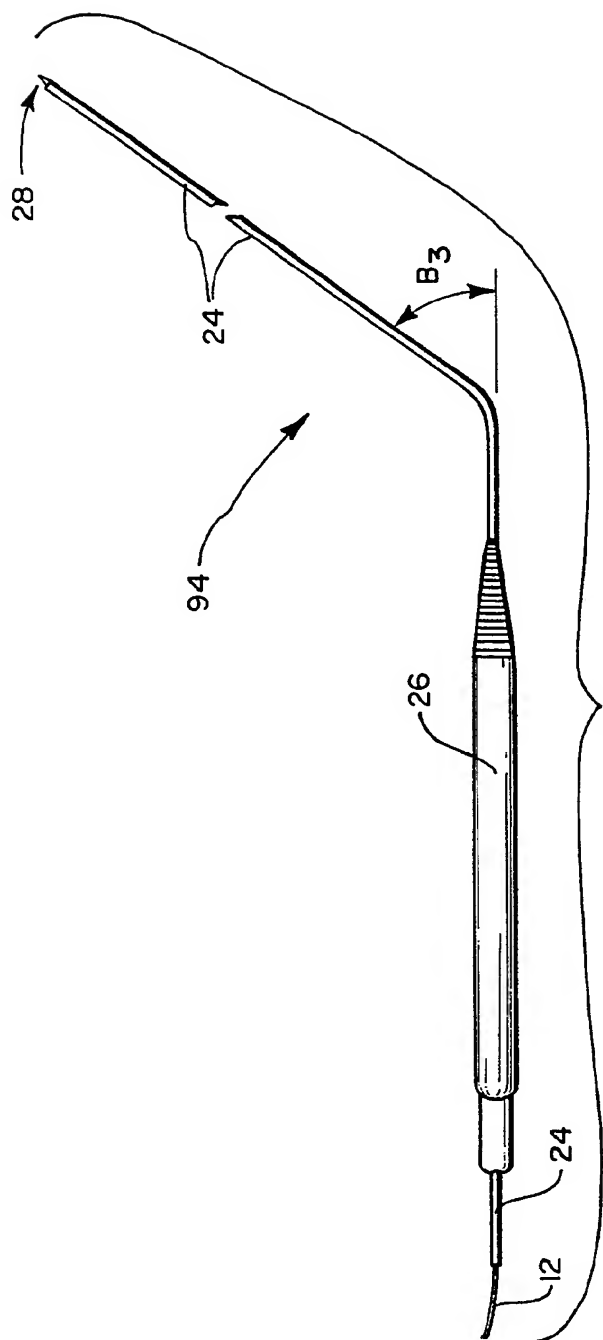


FIG. 5E

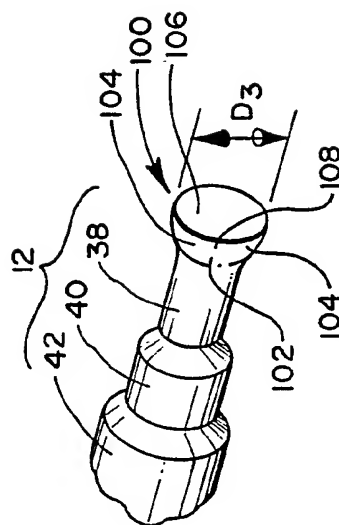


FIG. 6

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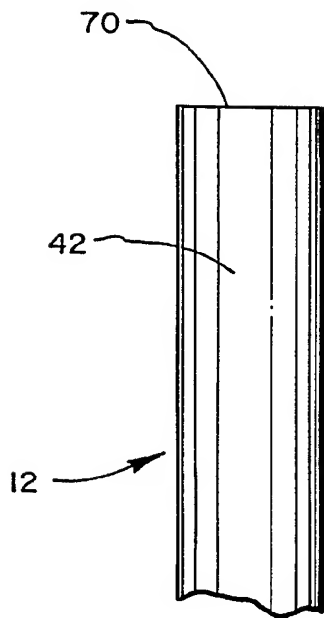


FIG. 7A

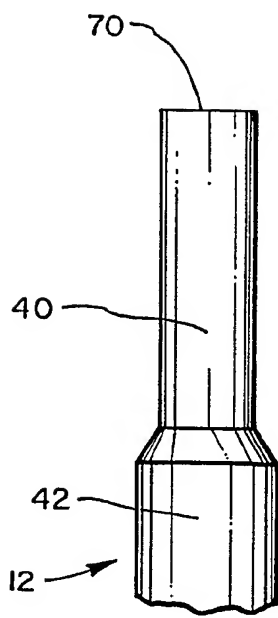


FIG. 7B

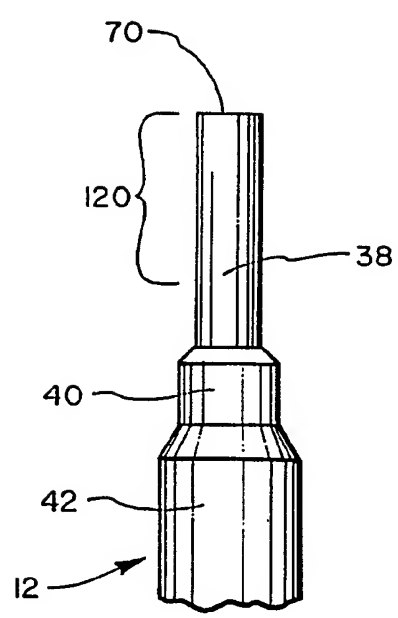


FIG. 7C

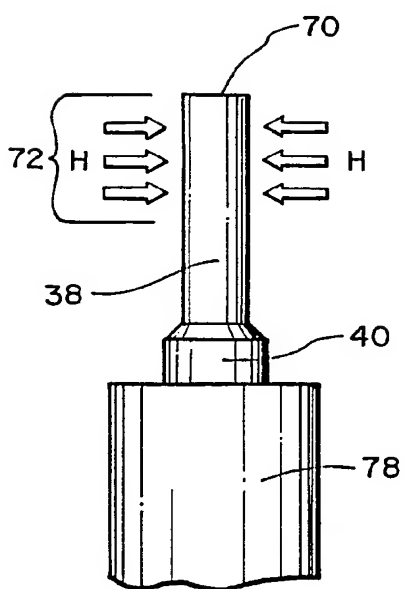


FIG. 7D

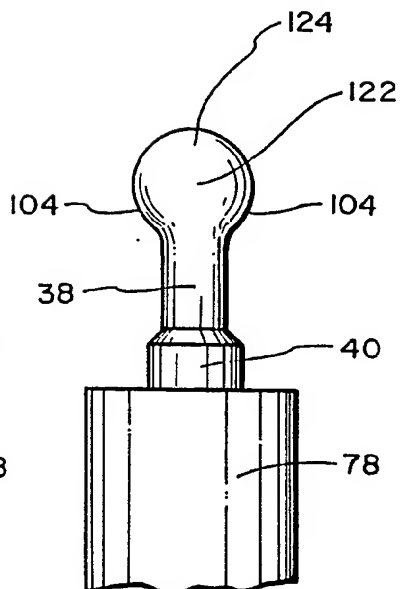


FIG. 7E

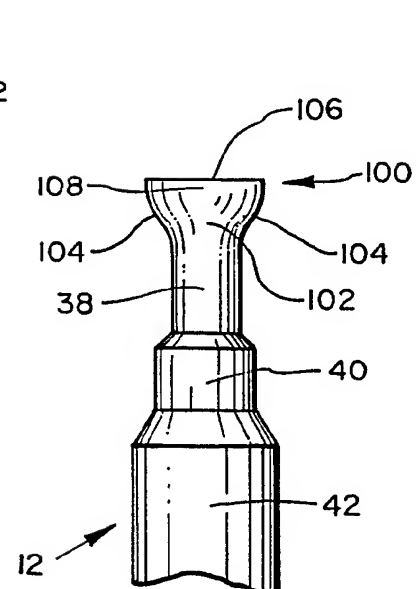


FIG. 7F

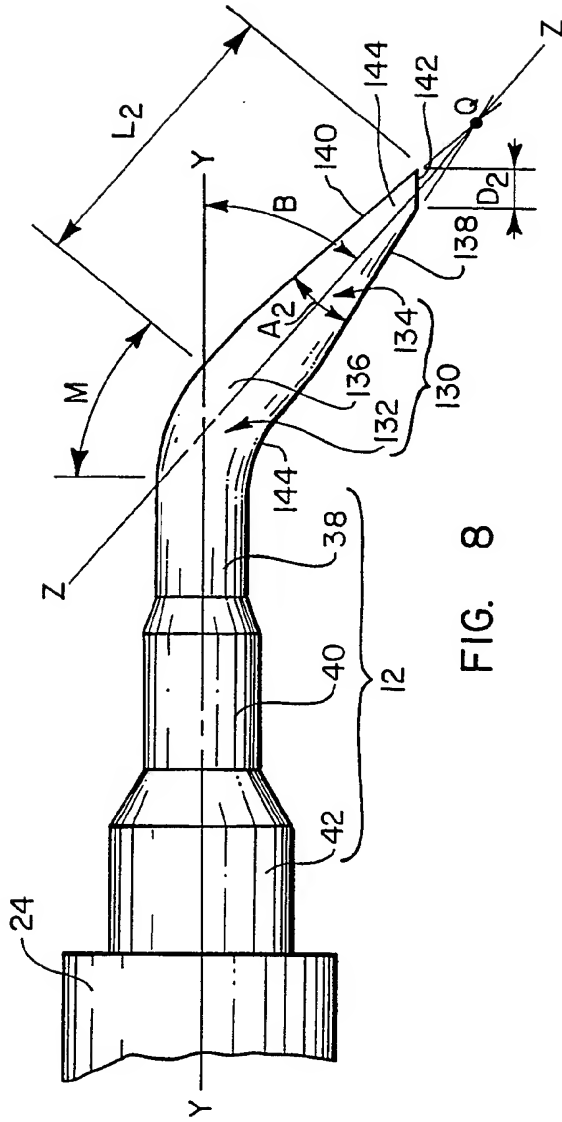


FIG. 8

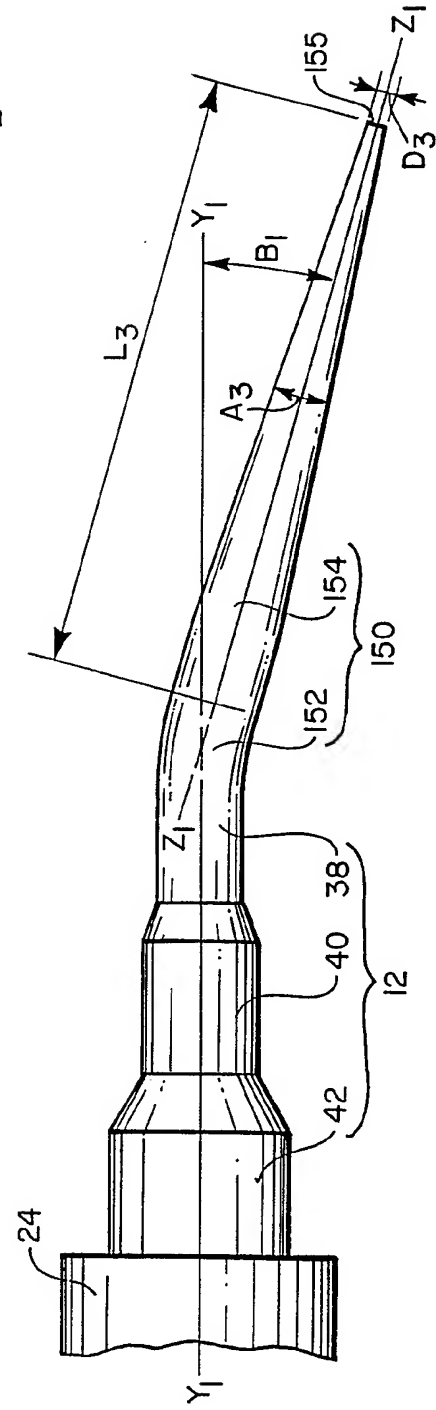


FIG. 9

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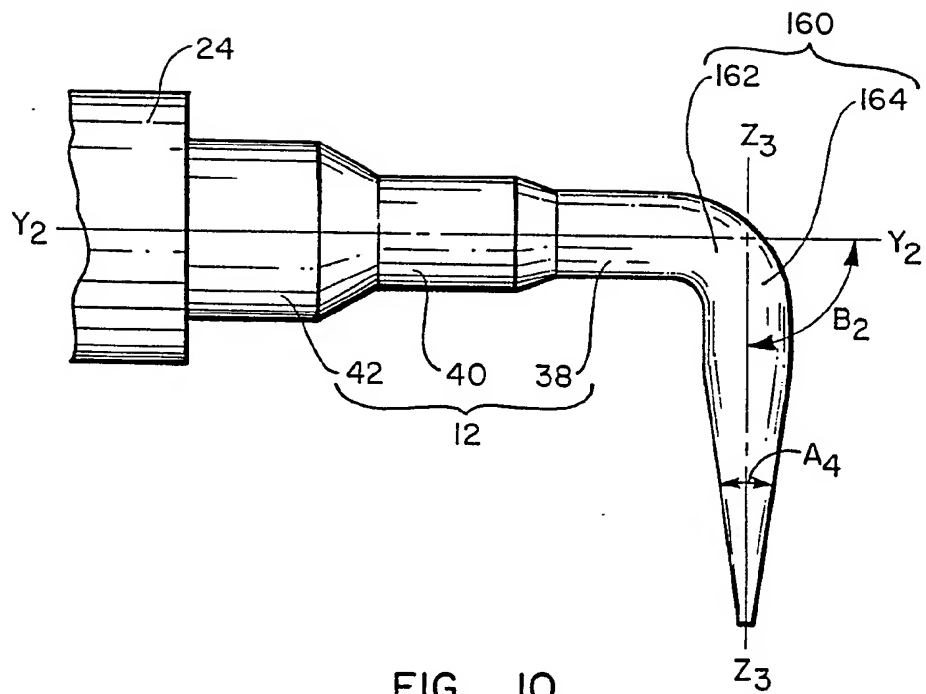


FIG. 10

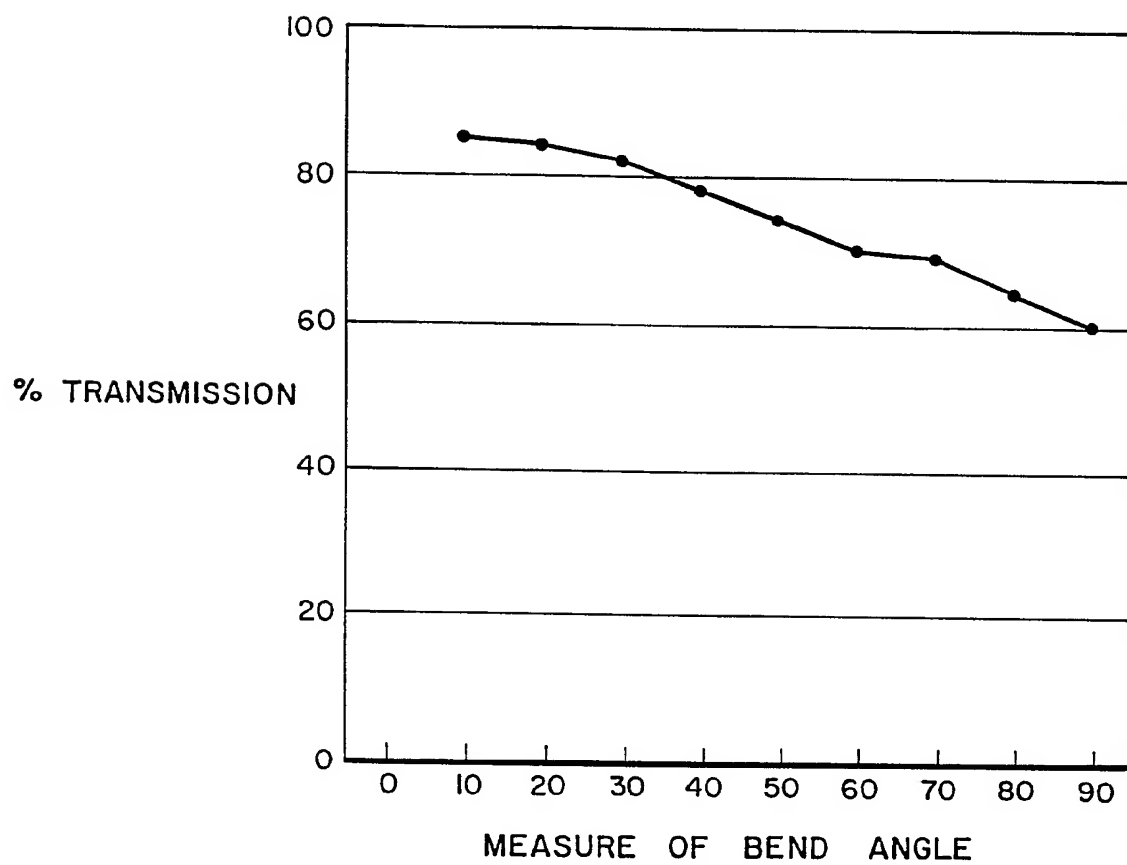


FIG. 11

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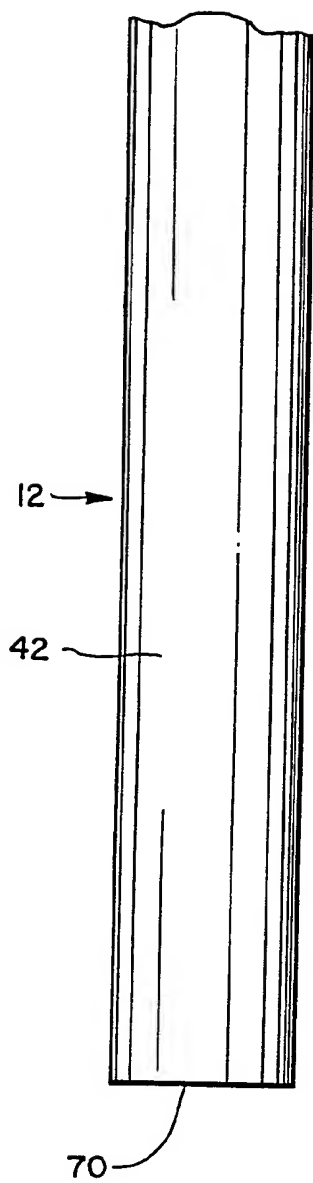


FIG. 12A

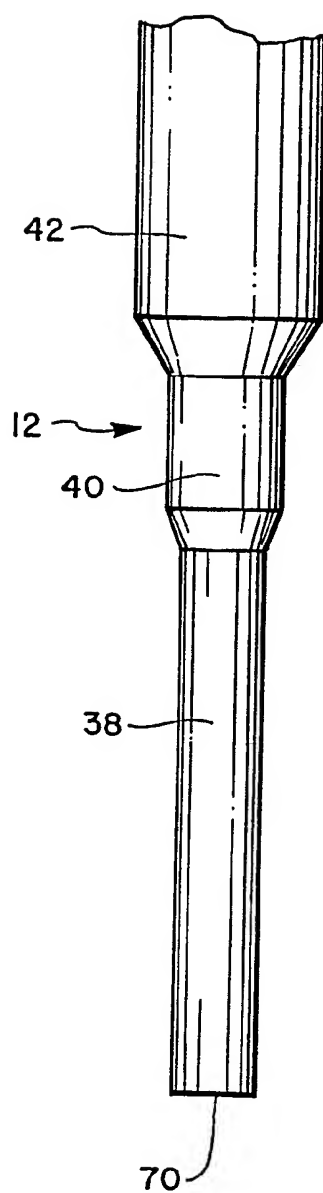


FIG. 12B

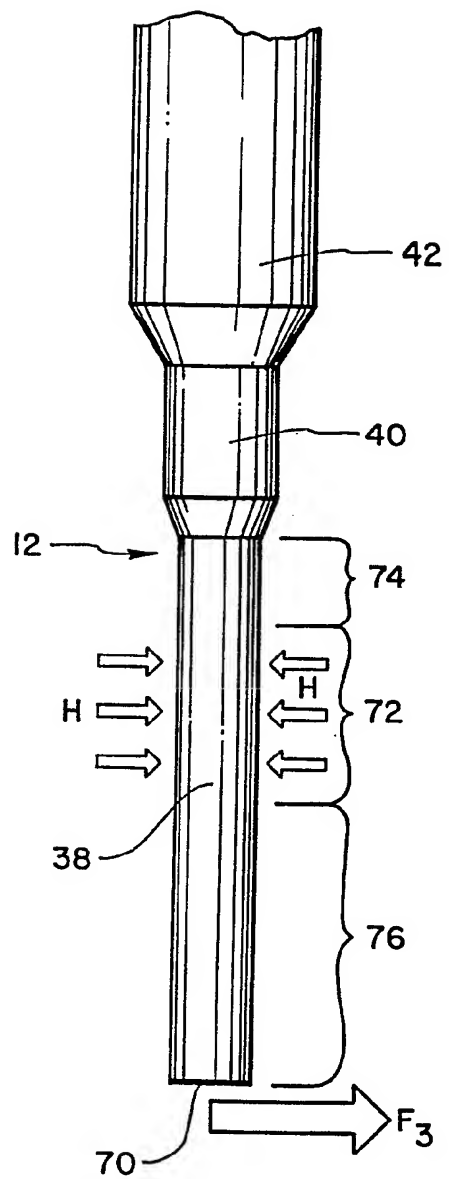
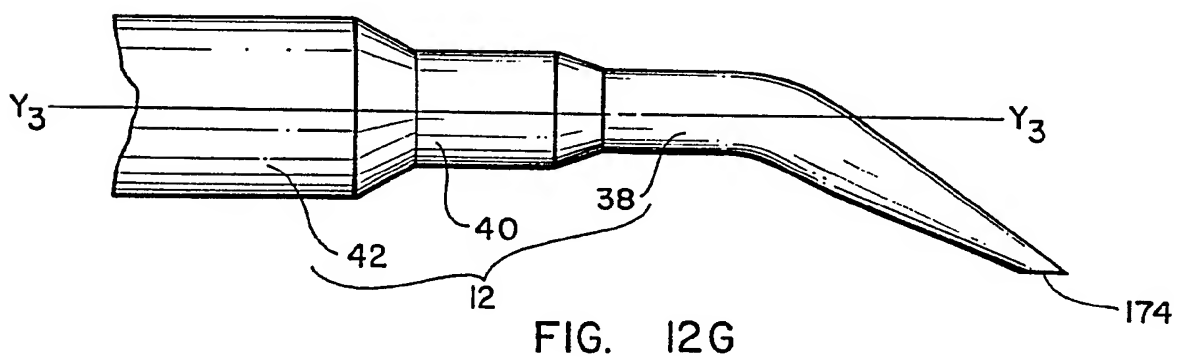
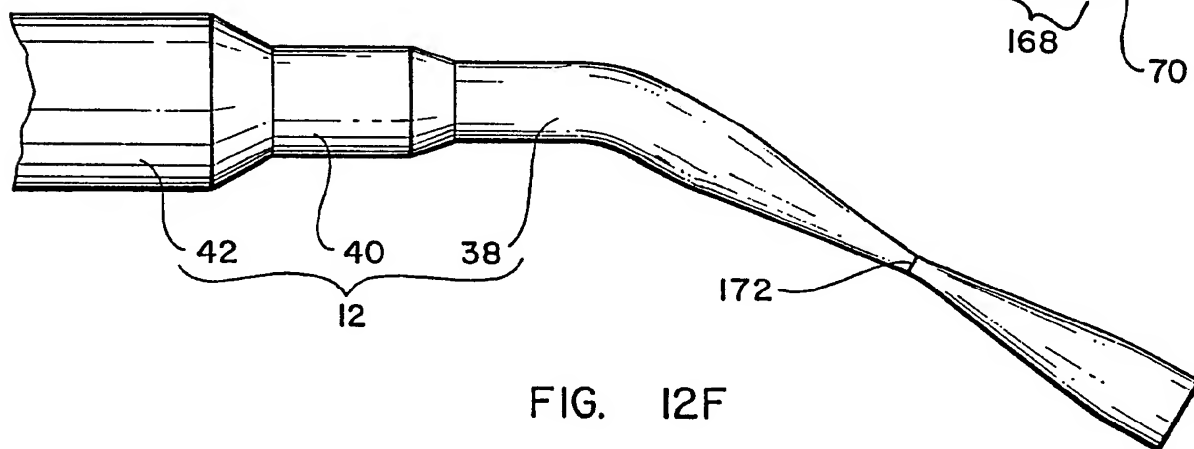
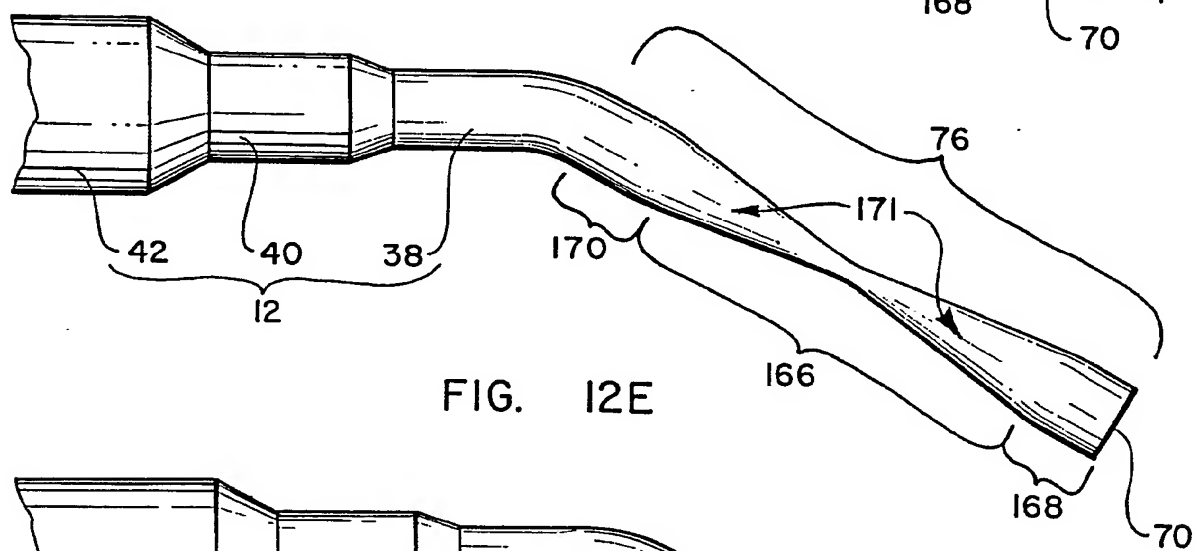
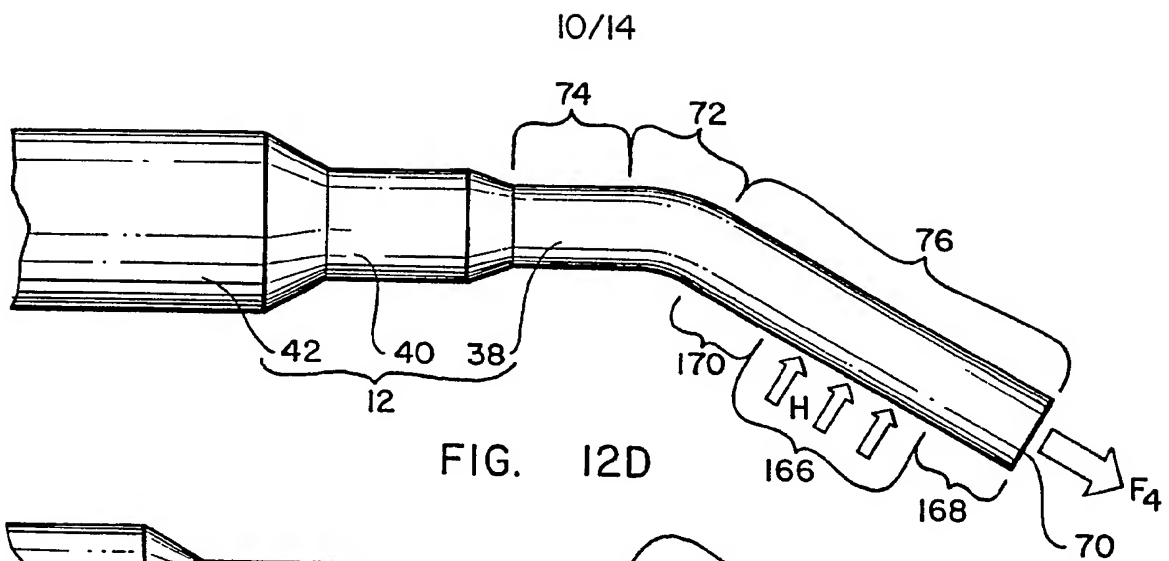
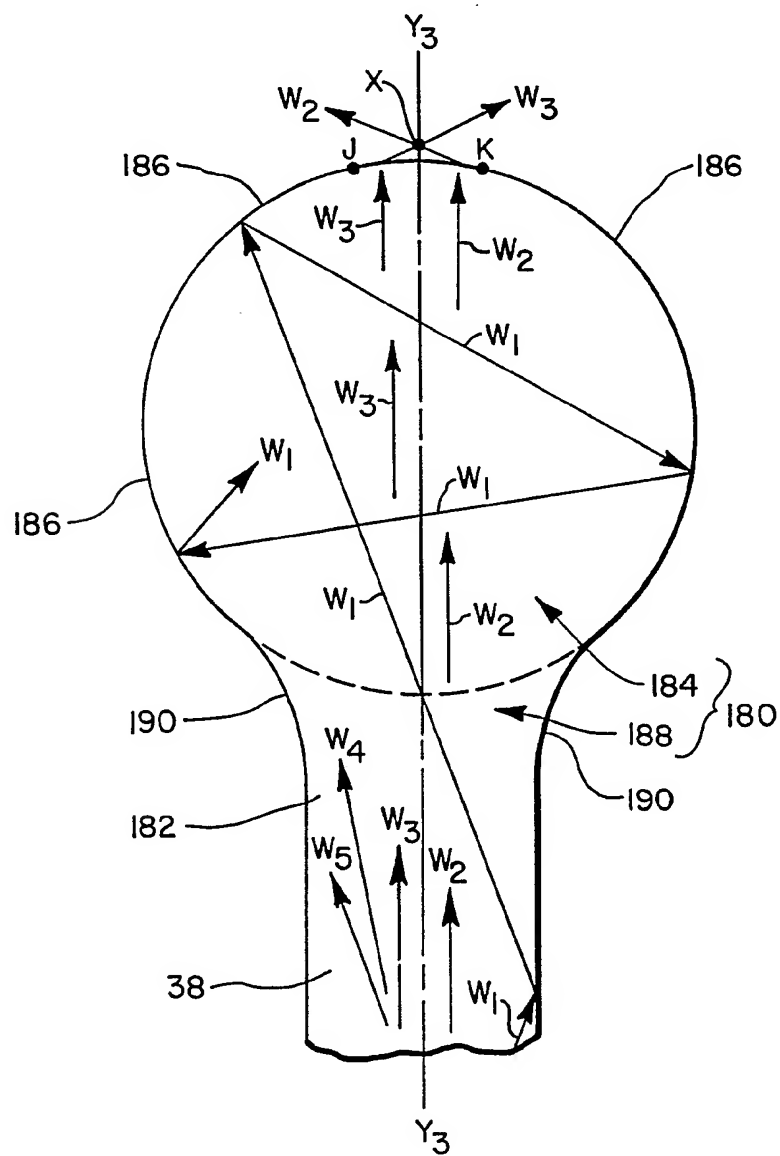
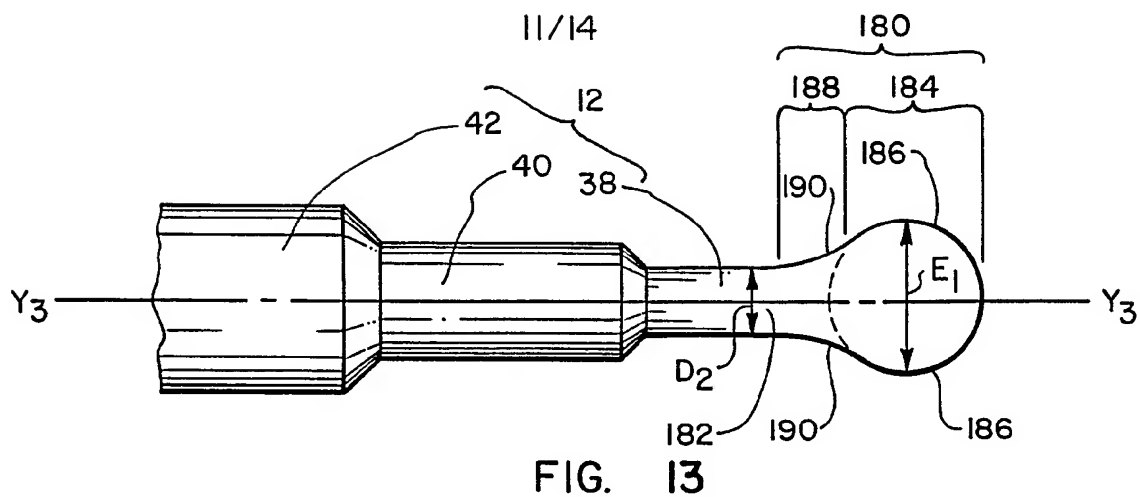


FIG. 12C





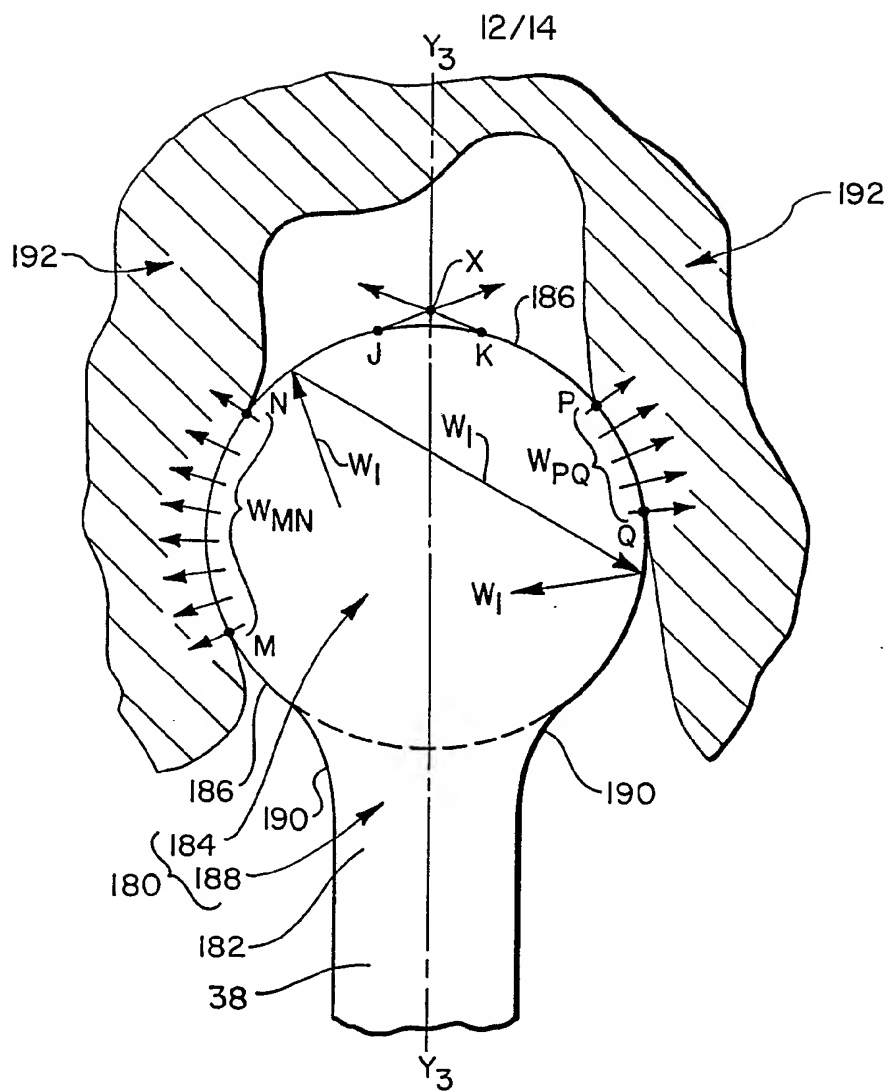


FIG. 15

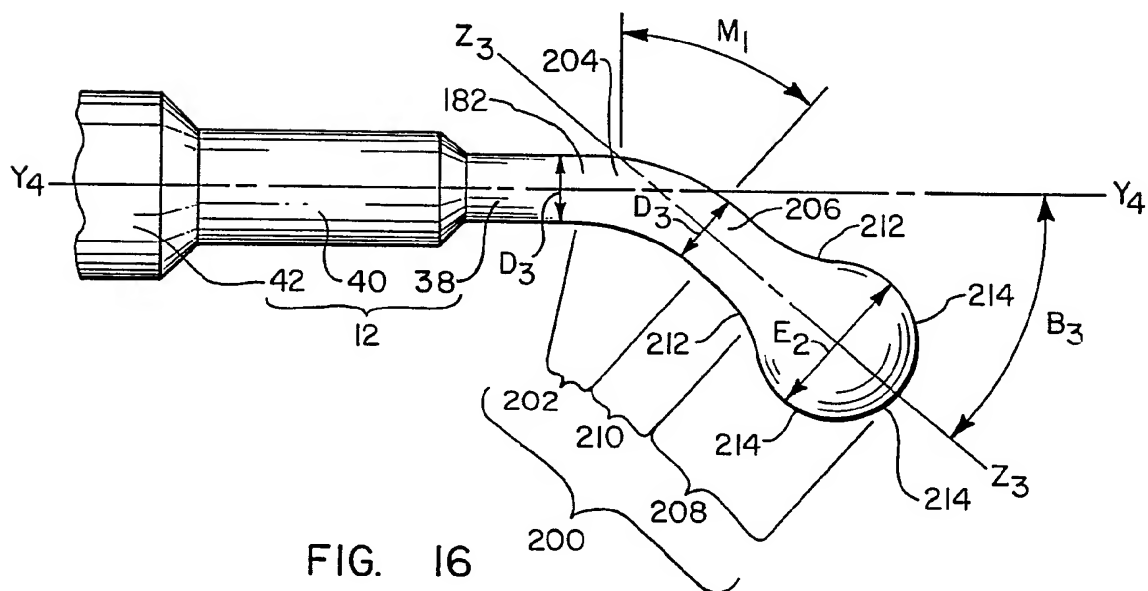


FIG. 16

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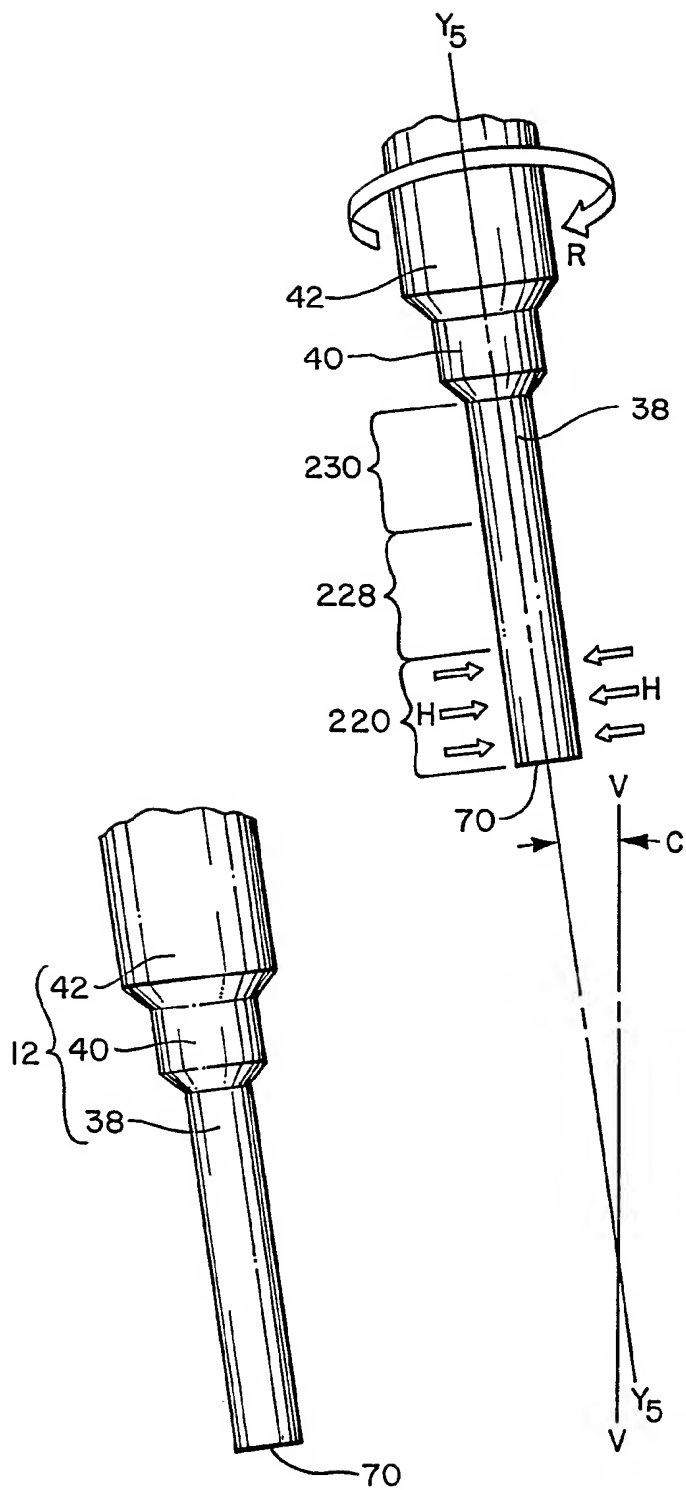


FIG. 17A

FIG. 17B

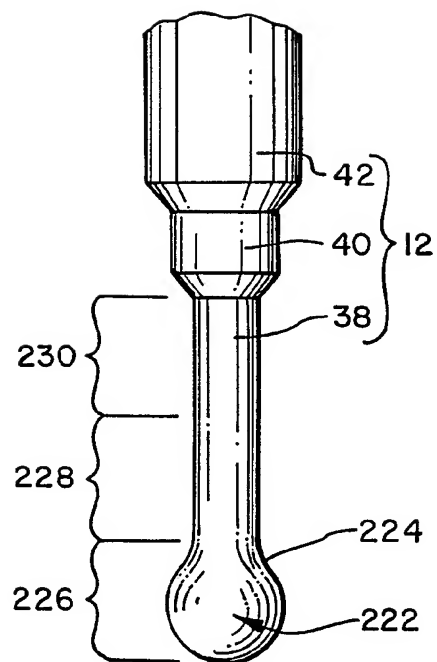
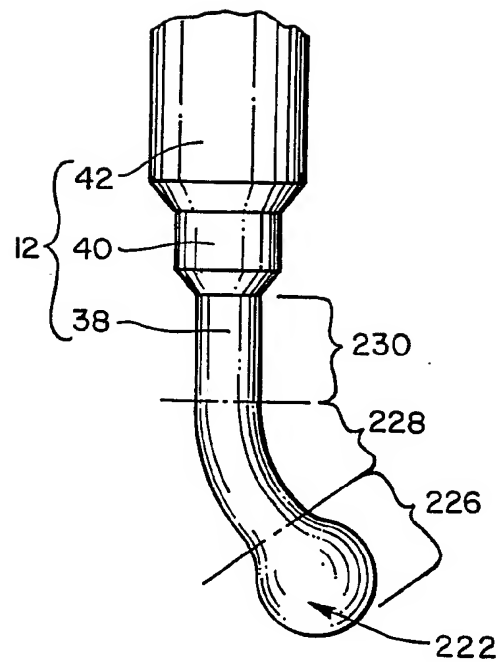
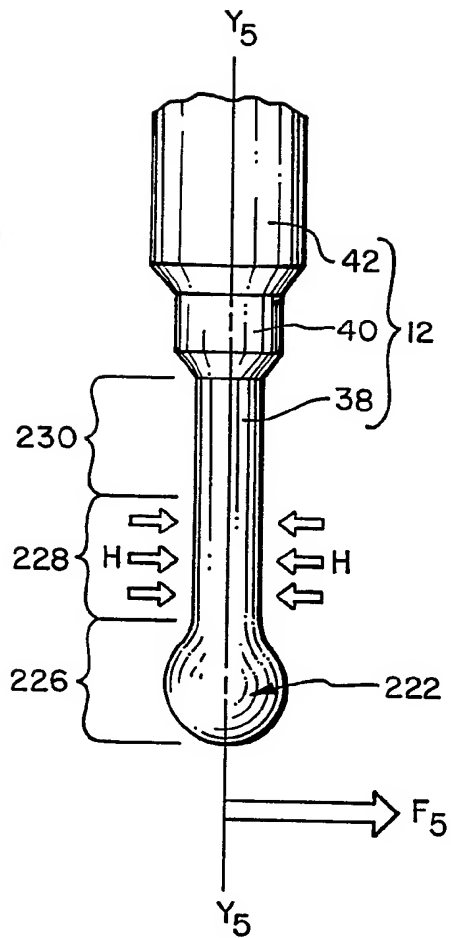


FIG. 17C



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/04658

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) : A61N 5/06

U.S. Cl : 128/395,397,398; 606/7,13-17

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System ¹

Classification Symbols

U.S. 128/395,347,348;
65/2,10.2,23,37,40,102;
606/7,13-17

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁶ | Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷ | Relevant to Claim No. ¹⁸

<p><u>X</u> <u>Y</u></p>	<p>EP,A 142,026 (RUSSO) 22 May 1985 See the entire document.</p>	<p>1-9,11-21, 32-34,39-47, 50-56,60-62, 64,67-70,73 10,22-31,35- 38,48,49,57- 59,63,65,66, 71,72,74-77</p>
<p><u>X</u> <u>Y</u></p>	<p>US,A 3,288,585 (CLARKE) 29 November 1966 See the entire document.</p>	<p>74,75 76,77</p>
<p>Y</p>	<p>US,A 4,826,431 (FUJIMURA) 02 May 1989 See the entire document.</p>	<p>10,22-31,34, 35,65</p>
<p>Y</p>	<p>US,A 4,849,859 (NAGASAWA) 18 July 1989 See the entire document.</p>	<p>34-38</p>

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IV. CERTIFICATION

Date of the Actual Completion of the International Search ²

13 NOVEMBER 1990

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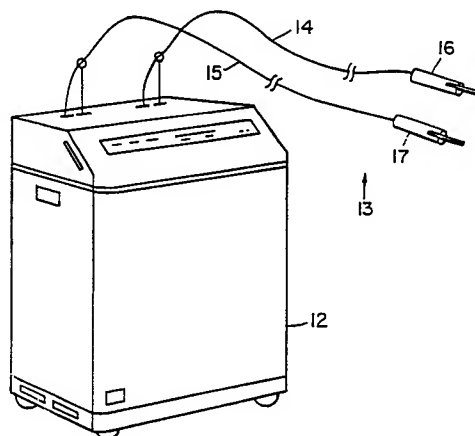
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(21) International Application Number: PCT/US91/01714 (22) International Filing Date: 14 March 1991 (14.03.91) (30) Priority data: 493,309 14 March 1990 (14.03.90) US (60) Parent Application or Grant (63) Related by Continuation US 493,309 (CIP) Filed on 14 March 1990 (14.03.90) (71) Applicant (for all designated States except US): CANDELA LASER CORPORATION [US/US]; 530 Boston Post Road, Wayland, MA 01778 (US).		(72) Inventors; and (75) Inventors/Applicants (for US only) : FURUMOTO, Horace [US/US]; 14 Woodridge Road, Wellesley, MA 02181 (US). CECCON, Harry, L. [US/US]; 8 Bond Street, Boston, MA 02118 (US). JONES, Christopher, J. [US/ US]; 18 Brookside Avenue, Lexington, MA 02173 (US). McMILLAN, Kathleen [US/US]; 16 Royal Crest Drive, #8, Marlboro, MA 01752 (US). (74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith & Reynolds, Two Militia Drive, Lexington, MA 02173 (US). (81) Designated States: AT (European patent), AU, BE (Euro- pean patent), BR, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (Eu- ropean patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>

(54) Title: APPARATUS FOR TREATING ABNORMAL PIGMENTATION OF THE SKIN



(57) Abstract

An apparatus comprises a first pulsed laser producing a beam of laser radiation having a wavelength between 345 and 600 nm for the treatment of epidermal pigmented lesions and a second pulsed laser producing a beam of laser radiation having a wavelength between 600 and 1100 nm for the treatment of dermal pigmented lesions. A delivery system is coupled to the apparatus and manipulated to deliver radiation to illuminate an area of a subject's skin. The delivery system of the present invention comprises a pair of flexible liquid core light guides having sufficient diameter to efficiently transmit high peak power intensity pulses of wavelengths between 345 and 1100 nm. For treatment of epidermal pigmented lesions, a first liquid core light guide delivers laser radiation of between 345 and 600 nm and preferably about 500 nm wavelength. The fluence is between 1 and 10 J/cm² at the skin and preferably between 2 and 4 J/cm². The pulse duration is less than 1 μsec and preferably less than 500 nsec. A 2 to 5 mm diameter spot is illuminated. For treatment of dermal pigmented lesions such as tattoos, a second liquid core light guide delivers laser radiation of between 600 and 1100 nm, fluence is between 1 and 10 J/cm² at the skin, pulse duration is less than 500. Once again, a 2 to 5 mm diameter spot is illuminated.

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APPARATUS FOR TREATING ABNORMAL
PIGMENTATION OF THE SKIN

Background of the Invention

Abnormal pigmentation of the skin is commonly seen
5 in dermatologic practice. A subject's skin may have
pigmentation abnormalities due to vascular lesions,
naturally occurring pigmented lesions, or tattoos.
Vascular lesions such as port wine stain birthmarks,
telangiectasia and hemangiomas are caused by the
10 abundance of enlarged blood vessels. Pigmented lesions
are non-vascular disfigurements of the skin caused by an
abnormally high concentration of melanin in localized
areas of the skin. Such pigmented lesions include
freckles, age or liver spots, cafe' au lait birthmarks,
15 lentigines, nevi, melanomes, nevus of Ota and lentigo
maligna. Tattoos may be divided into two categories,
including self-inflicted or traumatic tattoos. Traumatic
tattoos are created during accidents which cause a scrape
or abrasion such that a foreign material becomes imbedded
20 in the skin.

A myriad of therapeutic modalities including liquid
nitrogen, electrocautery and depigmenting chemicals have
been used to remove superficial pigmented lesions.
Although widely used, none have succeeded in destroying
25 the abnormal pigmented cells alone without damaging
adjacent structures and producing adverse effects like
hypopigmentation.

Over the last two decades, there have been several
reports describing the removal of superficial pigmented
30 lesions by a variety of lasers such as the excimer (351

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nm), argon (488,514 nm), ruby (694 nm), Nd:YAG (1060 nm), and CO₂ (10,600 nm) lasers. However, there has generally been damage to both pigmented and nonpigmented cells. Pigmented lesions treated by laser have included

5 lentigines, nevi, melanomas, oral hypermelanosis of Peutz-Jeghers syndrome, the nevus of Ota, and a lentigo maligna. The pigment depth of these laser-treated lesions has also varied significantly, from superficial lentigines in the epidermis to lesions lying deep in the

10 reticular dermis like the nevus of Ota.

Previous studies reporting "successful" removal of pigmented lesions have relied on clinical assessment rather than on histology and have used widely divergent wavelengths, pulse durations, energy densities and

15 spotsizes. There has been no effort to define laser parameters necessary for optimal removal of pigmented lesions.

Melanin, an endogenous cutaneous pigment which is most concentrated in the basal layer of the epidermis,

20 has an absorption spectrum that is highest in the ultraviolet range and gradually diminishes toward the infrared. Melanosomes are melanocyte-specific organelles densely packed with melanin. They vary in size according to their genetic origin; black skin typically containing

25 larger melanosomes than lightly pigmented, white skin. Based on melanosome size, the calculated thermal relaxation time for these organelles is around 10 nsec. On the other hand, melanocytes are approximately 7 μ m in diameter, with thermal relaxation times around 1 μ sec.

30 Thermal relaxation time in both instances is defined as the time taken for a structure to cool to 50% of its peak temperature immediately after laser exposure.

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Recent studies have applied the technique of selective photothermolysis to specifically destroy melanosomes using the XeF pulsed excimer in vitro and the Q-switched ruby lasers in vivo. Histologically, both
5 these studies demonstrated melanosomal injury that was associated with disruption of melanocytes as well as melanin-containing basal keratinocytes. In addition, there was also evidence of follicular damage after exposure of pigmented guinea pig skin to the Q-switched
10 ruby laser.

Selective photothermolysis has also been employed in other studies to treat tattoos. It was demonstrated that a Q-switched ruby laser is not effective for all types of tattoos, because tattoos are often multicolored. These
15 studies have shown that blue-black tattoos responded well to Q-switched ruby laser treatment, while green and yellow tattoos responded less than well and red tattoos responded poorly or not at all. Additionally, persistent hypopigmentation was a frequent occurrence.

20 Disclosure of the Invention

In accordance with the present invention, an apparatus produces a plurality of pulsed beams of laser radiation for the treatment of epidermal and dermal pigmentation abnormalities of the skin. By having the
25 capability to provide plural laser beams of different wavelengths (colors), the range of applications for which the apparatus is effective increases significantly. An apparatus capable of providing one of two beams of different wavelengths is believed to be sufficiently
30 effective for the majority of cases in therapeutic dermatology and plastic surgery involving treatment of non-vascular pigmentation abnormalities.

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The apparatus comprises a first pulsed laser producing a first beam principally for the treatment of epidermal pigmentation abnormalities and a second pulsed laser producing a second beam principally for the treatment of dermal pigmentation abnormalities. In one embodiment, the first laser is pulsed dye laser supported by a dye circulation system and the second laser is an alexandrite laser. The two lasers are coupled to a common power supply and storage system. The lasers are excited by a flashlamp means which may comprise a single coaxial flashlamp for exciting both lasers or a pair of coaxial flashlamps for separately exciting each laser. In another embodiment, the first laser is used to excite the second laser in a laser excited configuration. In this embodiment, the first laser is preferably a flashlamp excited pulsed dye laser and the second laser is preferably an alexandrite laser.

In accordance with one feature of the present invention, specific laser parameters are established to obtain effective treatment of epidermal and dermal pigmentation abnormalities while minimizing damage to normal pigmented cells. To that end, effective treatment of epidermal lesions with minimal damage has been obtained with a first laser having a wavelength of about 500 nm, a pulse duration of about 500 nsec, and fluence (energy density) of about 3 J/cm^2 at the skin. The spotsize may range from about 2 to 5 mm diameter, but preferably it is about 3 mm diameter. To minimize damage, wavelength of the first beam should be less than 600 nm. Due to known problems of mutagenesis, the wavelength should not be less than 345 nm. The fluence of the first beam may range from 1 to 10 J/cm^2 at the skin through the full range of wavelengths, but is

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preferably within the range of 2 to 4 J/cm² for 504 nm light. Pulse durations approaching 1 μsec may be used but at 1 μsec recurrence is expected. Shorter pulse durations should minimize damage to normal tissue.

5 To avoid pigmentary incontinence of the epidermal pigment resulting from laser irradiation and to get better access to dermal pigment to effectively treat dermal pigmentation abnormalities, a window is created in the epidermis using the above defined laser parameters
10 and the deeper cells are treated with the second laser having parameters specific to those cells. More specifically, it is expected that effective treatment with minimal damage may be obtained with the second laser having a wavelength of about 750 nm, a pulse duration of
15 about 100 nsec and an energy of about 1 J/cm² at the skin. The fluence at the skin for the second beam may range from 1 to 10 J/cm² through a range of wavelengths between 600 and 1100 nm, but it is preferably within the range of 1 to 4 J/cm² for 760 nm light. The spotsize may
20 range from about 2 to 5 mm diameter, but preferably it is about 3 mm diameter. The longer wavelengths are required to penetrate to depths associated with the location of dermal pigmentation abnormalities.

 In a typical dermatology procedure, treatment is
25 administered with a delivery system which is manipulated to deliver radiation to illuminate an area of a subject's skin. For effective treatment, the dual laser system requires pulse durations on the order of tens to hundreds of nanoseconds for potentially high intensity pulses.
30 Thus, the delivery system must be capable of transmitting high peak intensity pulses with low losses and must be flexible for convenience of use.

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To that end, one embodiment of the preferred delivery system of the present invention comprises a pair of flexible liquid core light guides having sufficient diameter to efficiently transmit high peak power intensity pulses of wavelengths between 345 and 1100 nm from the dual laser system. More specifically, a first liquid core light guide delivers the first beam of laser radiation of wavelength between 345 and 600 nm, fluence of 1 to 10 J/cm² at the skin and pulse duration of less than 1 μ sec to the handpiece for treatment of epidermal pigmented lesions. The first liquid core light guide has a liquid core comprising an aqueous inorganic salt solution within a flexible cladding which facilitates the transmission of laser radiation of wavelengths between 345 and 600 nm. The core diameter may be between 3 and 10 mm and preferably about 3 mm such that the first guide is capable of transmitting high peak intensity pulses. However, the liquid within the first guide does not effectively transmit radiation of wavelengths between 600 and 1100 nm due to the presence of chemical bonds involving hydrogen which significantly attenuate the radiation.

The second liquid core light guide delivers the second beam of laser radiation of wavelength between 600 and 1100 nm, fluence of 1 to 10 J/cm² at the skin and pulse duration of less than 500 nsec to the handpiece for treatment of dermal pigmentation abnormalities such as tattoos. The second guide has a liquid core comprising a liquid and housed within a flexible cladding. The liquid has a molecular structure characterized by the absence of chemical bonds which would cause absorption between wavelengths 600 and 1100 nm. As a minimum, the liquid is non-hydrogenous and comprises halogenated compounds.

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Preferrably, the liquid comprises halocarbons such as tetrachloroethylene or carbon tetrachloride, or a solution of inorganic salts in deuterium oxide. The index of refraction for the liquid is greater than the index of refraction for the cladding. The liquid core of the second light guide has a diameter between 3 and 10 mm and preferably about 5 mm such that the second guide is capable of transmitting high peak intensity pulses.

Another embodiment of the preferred delivery system of the present invention comprises a flexible liquid core light guide for efficiently transmitting high peak power intensity pulses of wavelengths between 345 and 1100 nm from the dual laser system. More specifically, the second light guide comprises a liquid capable of delivering laser radiation from the first laser for treatment of epidermal pigmentation abnormalities and from the second laser for treatment of dermal pigmentation abnormalities. In this embodiment, the light guide is coupled to both lasers and delivers radiation from the particular laser being employed for treatment.

Other advantages and features of the invention will become apparent from the following description of the preferred embodiments, and from the claims.

Brief Description of the Drawings

Fig. 1 illustrates a dual laser system with separate delivery systems.

Fig. 2 is an enlarged perspective view of the handpiece of Fig. 1.

Fig. 3 is a block diagram of a preferred embodiment dual laser system.

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Fig. 4 is a block diagram of another preferred embodiment dual laser system.

Fig. 5 is a block diagram of yet another preferred embodiment dual laser system.

5 Fig. 6 is a cross-sectional view of a liquid core light guide of Fig. 1.

Description of Preferred Embodiments

Pigmentation abnormalities may be removed from the skin by lasers provided that the lasers have the proper characteristics based on the principles of selective photothermolysis. These principles require the proper selection of wavelength (or color) of the laser to maximize absorption within the targeted lesion and minimize absorption by the surrounding normal tissue, organs or organelles. Selective photothermolysis also requires the precise selection of pulse duration of the laser beam which is determined by the thermal relaxation time of the target. Pulse duration should be shorter than the thermal relaxation so that only the targeted material is heated and the surrounding tissue is unaffected.

Pigmented lesions have broad band absorption characteristics with high absorption at shorter wavelengths (blue-violet) and decreasing monotonically to higher wavelengths (red). Additionally, it has been shown that shorter wavelength (blue-green) lasers treat superficial pigmented lesions better than longer wavelength (red) lasers. On the other hand, longer wavelength (red) lasers are more effective for treating dermal pigmentation abnormalities including deeper pigmented lesions and tattoos. However, it has been demonstrated that the long wavelength ruby red laser is

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not effective for tattoos. Blue and black tattoos respond well to ruby laser treatment, while green and yellow tattoos respond less well and red tattoos respond poorly. These results are predicable based on the
5 absorption characteristics of the tattoo pigments. It is therefore desirable to tailor the wavelength (color) of the laser radiation to the absorption characteristic of the targeted material within the skin.

In accordance with the present invention, a laser
10 system 12 provides two pulsed beams of laser radiation having distinct wavelengths which may be employed for the treatment of epidermal and dermal pigmented lesions of the skin (see Fig. 1). Although a laser system producing more than two different wavelength beams is within the
15 scope of this invention, discussion is limited to a laser system providing two different wavelength pulsed beams. Also, the specific parameters of each laser beam including wavelength, intensity and pulse duration are discussed in detail below.

20 A delivery system 13 is coupled to the laser system 12 and delivers the two laser beams to a pigmented region of the skin. In a preferred embodiment, the first laser beam is delivered through a first light guide 14 to a handpiece 16 and second laser beam is delivered through a
25 second light guide 15 to a handpiece 17. In another preferred embodiment, the delivery system may comprise only the second light guide 15 and the handpiece 17 (Fig. 5). In this embodiment, both laser beams are coupled to the guide 15 which delivers either beam to the skin for
30 treatment of pigmentation abnormalities. Alternatively, one or both laser beams may be delivered through an articulated arm (not shown). The features of the first and second light guides are discussed in detail below. A

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preferred handpiece, illustrated in Fig. 2, is model number 7040-00-6231 sold by Candela Laser Corporation. Two lenses in the handpiece image the distal end of the guide to a larger spot adjacent to the end of a positioning extension 18. By selection of the lenses, the spotsize can be varied. The spotsize may be between 2 and 5 mm diameter and is preferably about 3 mm diameter. By movement of the handpiece and irradiation of adjacent spots, a test site of about 0.5-1.0 cm x 0.5-1.0 cm may be irradiated at a selected dose.

In a preferred embodiment of the laser system, as shown in Fig. 3, the laser system 12 comprises a pair of laser systems 20 and 22. The laser systems comprise a pair of flashlamp excited pulsed lasers 21 and 23 having a common power supply/storage system 24. The lasers are excited by a flashlamp means which may comprise a single coaxial flashlamp (not shown) or a pair of coaxial flashlamps 26 and 27 for separately exciting the first and second laser 21 and 23 respectively. Preferably, the first laser 21 is a pulsed dye laser having a dye circulation system 28 and the second laser 23 is an alexandrite laser. Alternatively, both lasers may be pulsed dye lasers with separate circulation systems. Furthermore, one or both of the laser systems 20 and 22 may comprise any non-dye pulsed laser system such as a solid state laser.

In another preferred embodiment, shown in Fig. 4, a first laser system 20 is arranged to excite a second laser system 22 in a laser-excited configuration. Preferably, the first laser 20 is a flashlamp excited pulsed dye laser supported by a dye circulation system 28 and the second laser 32 is an alexandrite laser. In yet another preferred embodiment, shown in Fig. 5, the pair

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of laser systems 20 and 22 are coupled by an optical coupler 38 to the delivery system 13 comprising a single light guide 17. In any of the preferred embodiments, the laser systems 20 and 22 may comprise any combination of
5 the following lasers to provide a short wavelength beam and a long wavelength beam of laser radiation.

Accordingly, the first laser may be a dye laser, or a frequency doubled Neodymium, Nd:YAG, Nd:Glass, Nd:YLF, Ti:Sapphire, frequency doubled Alexandrite or excimer
10 laser. The second laser may be a dye laser or a solid state laser including a ruby, Ti:Sapphire, $\text{SM}^3\text{:YLF}$ or any chromium laser in assorted host materials KZnF_3 , ScBO_3 , LaLuGG, GSGG, YSGG, YGG, $\text{BeAl}_2(\text{SO}_3)_6$.

Specific laser parameters have been established for
15 the dual laser system to obtain effective treatment of epidermal and dermal pigmented lesions while minimizing damage to normal pigmented cells and are hereinafter discussed.

A wide range of experimental treatments have been
20 performed on the normally pigmented skin of miniature black pigs and those have been followed by extensive clinical studies. A first set of experiments was performed to identify shorter wavelengths in the green portion of the spectrum for the minimization of epidermal
25 damage, particularly pigmentary incontinence, as well as regeneration of normal pigment cells. A second set of experiments using the optimum laser wavelength of 504 nm has identified shorter pulse durations as preferred for minimizing epidermal damage. Finally, clinical studies
30 of human patients have demonstrated that laser light of the shorter wavelengths and shorter pulse durations is most effective in treating the epidermal pigmented lesions with treatment fluences at the skin of about 3

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J/cm². Limited human pigmented lesion studies have demonstrated lack of effectiveness in treating epidermal pigmented lesions at 694 nm and 750 nm.

In the experiments related to epidermal (superficial) pigmented lesions, a Model SLL500-M flashlamp-pumped tunable dye laser system supplied by Candela Laser Corporation has been used. The light was delivered through a 1 mm diameter optical fiber cable to a handpiece to illuminate a spot of 1 to 3 mm diameter with a single pulse. The handpiece used was a model number 7040-00-6231 supplied by Candela Laser Corporation.

In the first set of experiments on normal black pig skin, the tunable dye laser was tuned to 504, 590, 694, 720 and 750 nm using a variety of dye mixtures. The laser had a pulse duration of 500 nsec. Energy densities ranging from .25 to 3.0 J/cm² at 0.25 J/cm² increments, and at 4.0, 5.0, 6.0 and 7.0 J/cm² were delivered to pigmented skin at a spotsize of 3 mm diameter. The skin was irradiated at each energy density for each of the five wavelengths tested. Skin biopsies were taken at each energy density from each of the five wavelengths immediately and at 4, 16, 23 and 33 days after laser exposure. These experiments were published by Sherwood et al., "Effect of wavelength on cutaneous pigment using pulsed irradiation," The Journal of Investigative Dermatology, Vol. 92, No. 5, May 1989.

Exposure of skin to energy densities of at least 5 J/cm² for 590 and 694 nm and 4.0 J/cm² for 720 and 750 nm resulted in sub-epidermal clefts accompanied by epidermal necrosis. No sub-epidermal clefts or epidermal necrosis were observed after exposure of skin to 504 nm irradiation, not even at the highest energy density of

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7.0 J/cm². In addition to epidermal injury, dermal damage consisting of collagen bundle separation accompanied by changes in the tinctorial quality of the bundles were observed in biopsies taken from the skin exposed to 7.0 J/cm² at the four wavelengths other than 504 nm. The extent of dermal injury appeared dependent on the wavelength; the most severe occurring at 750 nm. From biopsies, pigmentary incontinence (pigment dropping to the dermal layer) was evident. Its severity increased with increased energy density and wavelength.

Although pigment was destroyed using all wavelengths, repigmentation occurred more rapidly for the 504 nm irradiation. For the 504 nm irradiation, repigmentation was complete by the thirty-third day after exposure. Repigmentation followed sequentially by order of wavelength, with the 750 nm irradiated skin taking up to six weeks for its pigment to return to normal.

In the second set of experiments, miniature black pig skin was again irradiated. Using a 504 nm laser and 3 mm diameter spotsize, the effect of pulse durations of 100, 150, 250 and 500 nsec at fluences from 1.5 to 4.0 J/cm², at 0.5 J/cm² increments, were examined. Biopsies were taken immediately and at 7, 14 and 28 days after irradiation and were processed for light microscopy. The most severe damage was observed in skin exposed to pulse durations of 250 and 500 nsec. Epidermal necrosis, dermal-epidermal separation and pigmentary incontinence were not only more severe, but also occurred at significantly lower fluences than was evident in skin exposed to 100 and 150 nsec pulse durations. Although the normal cells repigment, the unsightly damage remains.

In the final clinical studies with human patients, superficial benign cutaneous pigmented lesions had been

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5 treated by using the pulse irradiation. Fifty-two patients have been treated variously for the following: lentigines, solar keratoses/'lentignes', cafe' au lait, seborrheic keratoses, hyperpigmentation associated with morphoea, nevus spilus.

Generally, the superficial lesions have been exposed to 504 nm laser irradiation. Pulse durations of 250 nsec, 500 nsec and 1 μ sec have been used with fluence ranging from 1.5 to 3.5 J/cm² for each pulse duration. A 10 3 mm diameter spotsize was used with the 500 nsec and 1 μ sec pulse durations. Because of limits in energy available from the particular laser used, a 2 mm diameter spotsize was used with 250 nsec pulse durations. A 1 mm diameter spotsize was used in limited tests of 6 to 8 15 J/cm², but excessive dermal damage was noted. This is consistent with findings presented in Tan et al., "Spotsize effects on guinea pig skin following pulsed irradiation," The Journal of Investigative Dermatology, Vol. 90, No. 6, June 1988. At all pulse durations, 20 incomplete lightening was found at 2 J/cm² and 2.5 J/cm². The 3.0 J/cm² was found to be the most effective dose. The 3.5 J/cm² was only used in a limited number of tests where insufficient response was obtained at 3.0 J/cm² and was effective. With the 1 μ sec pulse duration, the 25 lesions cleared but recurred. At 500 nsec, nonrecurring clearance was obtained. At 250 nsec, clearance was also obtained, and we are awaiting final results. Clinical observations indicate minimal dermal damage without noticeable pigmentary incontinence.

30 With limited tests at 504 nm and 4 J/cm², some permanent loss of normal pigment and undesirable surface changes were noted. However, with appropriate selection of other parameters, higher fluences may be feasible.

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Limited tests of a 694 nm Q-switched ruby laser having a pulse duration of 20 nsec and fluence of 5 J/cm² proved ineffective in removing the superficial lesions. Similarly, a Q-switched alexandrite laser of 760 nm, 100 nsec and 3 J/cm² was ineffective in treating the superficial lesion with a 2mm spotsize.

Limited tests at 577 nm, 360 nsec resulted in clearance of the lesion but with recurrence. However, lesions are expected to be effectively treated with that wavelength at shorter pulse durations. To minimize adverse effects, particularly due to pigmentary incontinence, wavelengths of about 600 nm or less are judged best from the first set of experiments.

Although 504 nm is the shortest wavelength tested, it is the most effective, and it is expected that shorter wavelengths within the melanin absorption spectrum will provide desirable results. Due to concerns for mutagenesis, wavelengths of less than 345 nm should not be used. It is postulated that the shorter wavelengths are most effective with least damage because they are absorbed by blood in the dermis and thus create thermal effects which minimize pigmentary incontinence.

It is expected that the acceptable fluence range at the skin is a function of wavelengths. At 504 nm, some effect on melanin is noted at 2 J/cm², and damage is seen above 4 J/cm². The depth of penetration in caucasian skin, which is inversely related to absorption, for 350 nm, 500 nm, 600 nm and 700 nm is about 60 μ , 230 μ , 550 μ and 750 μ , respectively. Thus, expected ranges of effect without damage, based on the 2 to 4 J/cm² range at 504 nm, is about 0.5 to 1.0 J/cm² for 345 nm, and 5 to 10 J/cm² for 600 nm. In general, it is expected that fluences of 1 to 10 J/cm² at the skin will be used for

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wavelengths of 345 nm to 600 nm. Thus, the first laser configured to provide a beam having these parameters may be employed to effectively treat epidermal pigmentation abnormalities.

5 On the other hand, treatment of pigmentation abnormalities in the dermis are also of interest, and longer wavelengths have been shown to be more effective due to greater depths of penetration. Tattoo treatment with a Q-switched ruby laser was studied by clinical
10 assessment as presented in Taylor et al., "Treatment of Tattoos by Q-Switched Ruby Laser," Arch. Dermatology, Vol 126, July 1990. The tattoos were exposed to 694 nm laser irradiation. Pulse durations of 40 to 80 nsec with fluence ranging from 1.5 to 8 J/cm² for each pulse
15 duration. All tattoos contained blue-black pigment and a few also had small areas of red, yellow, or green. It was demonstrated that the blue-black tattoos responded well to ruby laser treatment. However, the green and yellow areas responded less than well and the red areas
20 responded poorly or not at all.

 A problem encountered with laser treatment using longer wavelength beams is that of pigmentary incontinence where pigment from the epidermis is driven to the lower dermis. One means of treating the deeper
25 lesions with longer wavelengths without pigmentary incontinence is to remove the pigment in the epidermis using the shorter wavelengths and subsequently treat the lower regions with longer wavelengths before normal epidermal pigment returns. Thus, the shorter wavelengths
30 remove the pigment from the epidermis to create a window through which the light can pass into the dermis. Without pigment in the epidermis, illumination using the

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longer wavelengths cannot cause the pigmentary incontinence.

Effective treatment with minimal damage should be achieved with the second laser having a wavelength of about 750 nm, a pulse duration of about 100 nsec and a fluence of about 1 J/cm^2 at the skin. The second beam may provide a fluence ranging from 1 to 10 J/cm^2 at the skin through a range of wavelengths between 600 and 1100 nm. The longer wavelengths are optimal to achieve the depths of penetration associated with deeper pigmentation abnormalities including pigmented lesions and tattoos.

Based on the aforementioned tests, the present invention comprises a pair of lasers each providing a pulsed beam of laser radiation having specific parameters for obtaining effective treatment of epidermal and dermal pigmentation abnormalities while minimizing damage to normal pigmented cells. Effective treatment of epidermal pigmentation abnormalities may be achieved by employing a first beam having a wavelength between 345 and 600 nm, a pulse duration of less than $1 \mu\text{sec}$, and a fluence between 1 and 10 J/cm^2 at the skin. Additionally, effective treatment of dermal pigmentation abnormalities may be achieved by employing a second beam having a wavelength between 600 and 1100 nm, a pulse duration of less than 500 nsec and a fluence between 1 and 10 J/cm^2 at the skin. In a typical dermatology procedure, such treatment is administered by delivering laser radiation from the lasers to the skin with a delivery system.

Because the present invention requires pulse durations on the order of tens of nanoseconds to hundreds of nanoseconds and potentially high power densities, the delivery system must be capable of transmitting high peak intensity pulses with minimal losses and must be flexible

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for convenience of use. An articulated arm multiple mirror system has been used for high peak power applications in a dermatology procedure and may be employed. However, an articulated arm is bulky, cumbersome and difficult to align. Multifiber bundle cables are not appropriate because of high transmission losses related to the core/clad ratio. A flexible solid core single optical fiber is generally one of the most convenient delivery means for delivering a beam of laser radiation to illuminate a pigmented region of skin. A solid core fiber smaller than about 1 mm in diameter would be required because a larger fiber is too rigid. However, the maximum power density a 1 mm solid fiber can transmit is about 5 MW/mm^2 . Since peak laser beam intensities in the present invention may be up to ten times the maximum power density of the fiber (i.e. up to about 46 MW/mm^2), the fiber will be damaged or destroyed. A large diameter fiber would be required to handle the peak intensities, but such a fiber would be inflexible. Thus, solid core single optical fibers are not suitable delivery systems for the dual laser system.

The present invention employs a delivery system capable of transmitting high peak intensity pulses of wavelength between 345 and 1100 nm with minimal loss and which is flexible for convenience of use. In one preferred embodiment, shown in Fig. 1, the delivery system 13 comprises a pair of liquid core light guides 14 and 15 for delivery of laser radiation in dermatology procedures. The light guides are flexible and have a sufficient core diameter to transmit high peak intensity pulses of laser radiation with low losses. More specifically, the first liquid core light guide 14 delivers the first beam of laser radiation of wavelength

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between 345 and 600 nm, fluence of 1 to 10 J/cm² at the skin and pulse duration of less than 1 μsec to the handpiece 16 for treatment of epidermal pigmentation abnormalities. The second liquid core light guide 15 delivers the second beam of laser radiation of wavelength between 600 and 1100 nm, fluence of 1 to 10 J/cm² at the skin and pulse duration of less than 500 nsec to the handpiece 17 for treatment of dermal pigmentation abnormalities such as deeper pigmented lesions and tattoos.

A cross-sectional view of a liquid core light guide 40 is presented in Fig. 6. In one embodiment, the guide has a liquid core 42 comprising a liquid 43 which allows the transmission of light having a wavelength between 345 and 600 nm through the guide. The liquid core is housed in a flexible, thermostable, plastic cladding 44. The cladding has a lower refractive index than the liquid, producing total internal reflection at the core/clad interface such that light may be transmitted around bends in the light guide. Thus, the flexible guide transmits light independent of its configuration. The guide has an core diameter in the range of 3 to 10 mm and preferably about 3 mm such that the guide is capable of transmitting high peak power density pulses of laser radiation. These laser pulses enter and exit the guide 40 at a pair of silica rod windows 45 which also seal liquid with the guide. A metallic monocoil tube 46 surrounding the cladding has tooth-like contour which facilitates flexibility. A pair of end pieces 50 fasten around the windows and secure the cladding and the monocoil tube. An outer sleeve 48 encloses the monocoil tube and provides outer mechanical protection.

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Experiments have shown that a flexible liquid core light guide, made by Lumatec GmbH, having an aqueous inorganic salt solution within the liquid core, performs well in the spectral region from about 400 to 600 nm.

5 More specifically, the light guide 14 (made by Lumatec) has been used with a laser which produces 2 J, 300 nsec, 1 to 10 J/cm² pulses at a wavelength of 510 nm to effectively treat epidermal pigmented lesions.

10 Although the first liquid core light guide 14 has been shown to effectively deliver pulsed laser radiation in the spectral range from about 400 to 600 nm, it does not effectively transmit laser radiation of wavelengths between 600 and 1100 nm (red and near infrared wavelengths). The poor transmission capability of the
15 liquid of the first guide in the red and near infrared spectral range is due to the presence of chemical bonds involving hydrogen in the molecular structure of the liquid in the core. Overtone and combination bands of fundamental frequencies associated with such bonds lead
20 to absorption coefficients which are large enough to significantly attenuate the beam of pulsed laser radiation over distances required for convenient delivery (approximately 1.5 meters). Thus, to effectively
25 transmit laser radiation from the second laser, the second liquid core light guide must employ a liquid having no chemical bonds involving hydrogen or any other bonds which lead to absorption in the range of 600 to 1100 nm. Further, it has been determined that the liquid must satisfy other criteria relating to its physical
30 properties including low volatility, low gain coefficients for stimulated scattering and acceptable index of refraction as explained below.

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Two classes of chemical compounds having no chemical bonds that lead to the aforementioned absorption are completely deuterated compounds and halogenated compounds, specifically halocarbons. Within these two classes, the selected compound must be a liquid so that the guide remains flexible. Additionally, the compound must have low gain coefficients which provide an indication of the likelihood of stimulated scattering processes (Brillouin and Raman scattering) for a given laser peak power density. The gain coefficients must be sufficiently low such that the peak power density to be transmitted is below the critical intensity for the threshold of these non-linear scattering effects. Furthermore, the refractive index of the liquid must be greater than the refractive index of the cladding for the guide to transmit radiation with minimal losses. If an otherwise suitable liquid comprising a deuterated compound such as deuterium oxide has an unacceptably low index of refraction, a solute such as an inorganic salt may be added to increase its index to an acceptable value.

A light guide comprising the halocarbon carbon tetrachloride has been tested as the core liquid. In accordance with the above-described parameters, the light guide cladding material had an index of refraction of about 1.4 and the core liquid had an index of refraction of about 1.5. Alexandrite laser pulses at a wavelength of 760 nm, energy of 1 J and 55 ns pulse duration were successfully transmitted at 80% over 1.5 meters in guide having a 5 mm diameter core. The output spectrum from the guide was observed and showed no evidence of wavelength shifts produced by stimulated scattering. Additionally, the halocarbon tetrachloroethylene has been

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tested with alexandrite laser pulses up to 600 mJ and demonstrates the same percentage transmission.

In another preferred embodiment, shown in Fig. 5, the delivery system 13 comprises a single liquid core light guide 15 for efficiently transmitting high peak power intensity pulses of wavelengths between 345 and 1100 nm from the dual laser system. The light guide 15 comprises a liquid 43 capable of transmitting laser radiation in the wavelength range of the first laser as well as the second laser. As such, the light guide 15 is coupled to both lasers via an optical coupler 38 and delivers radiation provided by the first laser for treatment of epidermal pigmentation abnormalities and radiation provided by the second laser for treatment of dermal pigmentation abnormalities.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims. For example, other classes of chemical compounds having no chemical bonds which lead to absorption within the 600 to 1100 nm range may be used. Thus, the liquid within the second light guide may comprise silicate compounds or nitrile compounds.

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CLAIMS

1. An apparatus for treating epidermal and dermal
pigmentation abnormalities of the skin comprising:
a first pulsed laser for treating epidermal
5 pigmentation abnormalities by providing a first beam
of wavelength between 345 and 600 nm, fluence of 1
to 10 J/cm² at the skin and pulse duration of less
than 1 μ sec;
a second pulsed laser for treating dermal
10 pigmentation abnormalities by providing a second
beam of wavelength between 600 and 1100 nm, fluence
of 1 to 10 J/cm² at the skin and pulse duration of
less than 0.5 nsec; and
a delivery system coupled to the first and
15 second lasers for delivery of the first and second
laser beams to illuminate the epidermal and dermal
pigmented lesions respectively.
2. An apparatus as claimed in Claim 1 wherein the first
20 laser is a dye laser and the second laser is an
alexandrite laser.
3. An apparatus as claimed in Claims 1 wherein the
first and second lasers are dye lasers.
4. An apparatus as claimed in Claim 1, 2 or 3 wherein
25 the first laser produces a beam of about 500 nm
wavelength, 3 J/cm² fluence at the skin, and 500
nsec or less pulse duration.

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5. An apparatus as claimed in Claim 1, 2, 3 or 4 wherein the delivery system illuminates a region of about 2 to 5 mm diameter.
6. An apparatus as claimed in Claim 1, 2, 3, or 4 wherein delivery system illuminates a region of about 3 mm diameter.
7. An apparatus as claimed in Claim 1, 2, 3, 4, 5, 6 or 7 wherein the delivery system comprises a flexible liquid core light guide for delivery of the first and second laser beams.
8. An apparatus as claimed in Claim 1, 2, 3, 4, 5, or 6 wherein the delivery system comprises a flexible liquid core light guide for delivery of the second laser beam.
9. An apparatus as claimed in Claim 7 or 8 wherein the liquid core light guide comprises a liquid having a molecular structure characterized by the absence of chemical bonds that cause the absorption of light having wavelengths between 600 and 1100 nm.
10. An apparatus as claimed in Claim 7 or 8 wherein the liquid core light comprises a non-hydrogenous liquid.
11. An apparatus as claimed in Claim 9 or 10 wherein the liquid comprises halogenated compounds.
12. An apparatus as claimed in Claim 9 or 10 wherein the liquid has a molecular structure which comprises halocarbons.

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13. An apparatus as claimed in Claim 9 or 10 wherein the liquid comprises tetrachloroethylene.
14. An apparatus as claimed in Claim 9 or wherein the liquid comprises deuterium oxide and inorganic salts.
15. An apparatus as claimed in Claim 9 or 10 wherein the liquid comprises carbon tetrachloride.
16. An apparatus as claimed in Claim 9 or 10 wherein the guide has a core diameter of about 5 mm.
- 10 17. An apparatus as claimed in Claim 9, 10, 11, 12, 13, 14, 15 or 16 wherein the liquid core light guide further comprises a flexible, thermostable cladding in which the liquid is located, wherein the liquid has a refractive index which is greater than the cladding refractive index.
- 15
18. An apparatus as claimed in Claim 1, 2, 3, 4, 5, 6 or 7 wherein the delivery system comprises a liquid core light for delivery of the first laser beam and an articulated arm for delivery of the second laser beam.
- 20
19. An apparatus as claimed in Claim 8 wherein the delivery system comprises a second flexible liquid core light for delivery of the first laser beam.

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20. A dermatology laser apparatus comprising:
a pulsed laser for dermatology procedures on a subject's skin by providing a beam of wavelength between 345 and 1100 nm, fluence of 1 to 10 J/cm² at the skin and pulse duration of less than 1 μ sec; and
5 a flexible liquid core light guide for delivery of the beam to illuminate an area on the subject's skin.
21. An apparatus as claimed in Claim 20 wherein the
10 light guide has a core diameter between 3 and 10 mm.
22. An apparatus as claimed in Claim 20 or 21 wherein the light guide has a core diameter of about 5 mm.
23. An apparatus as claimed in Claim 19, 20, 21 or 22 wherein the light guide further comprises a
15 flexible, thermostable cladding in which a liquid is located, the liquid having a greater refractive index than the cladding.
24. An apparatus as claimed in Claim 23 wherein the
20 light guide further comprises a pair of windows located at each end of the guide and which seal a liquid within the cladding and a flexible metallic monocoil tube enclosing the cladding.
25. An apparatus as claimed in Claim 19, 20, 21, 22, 23 or 24 wherein the liquid core light guide comprises
25 a non-hydrogenous liquid.

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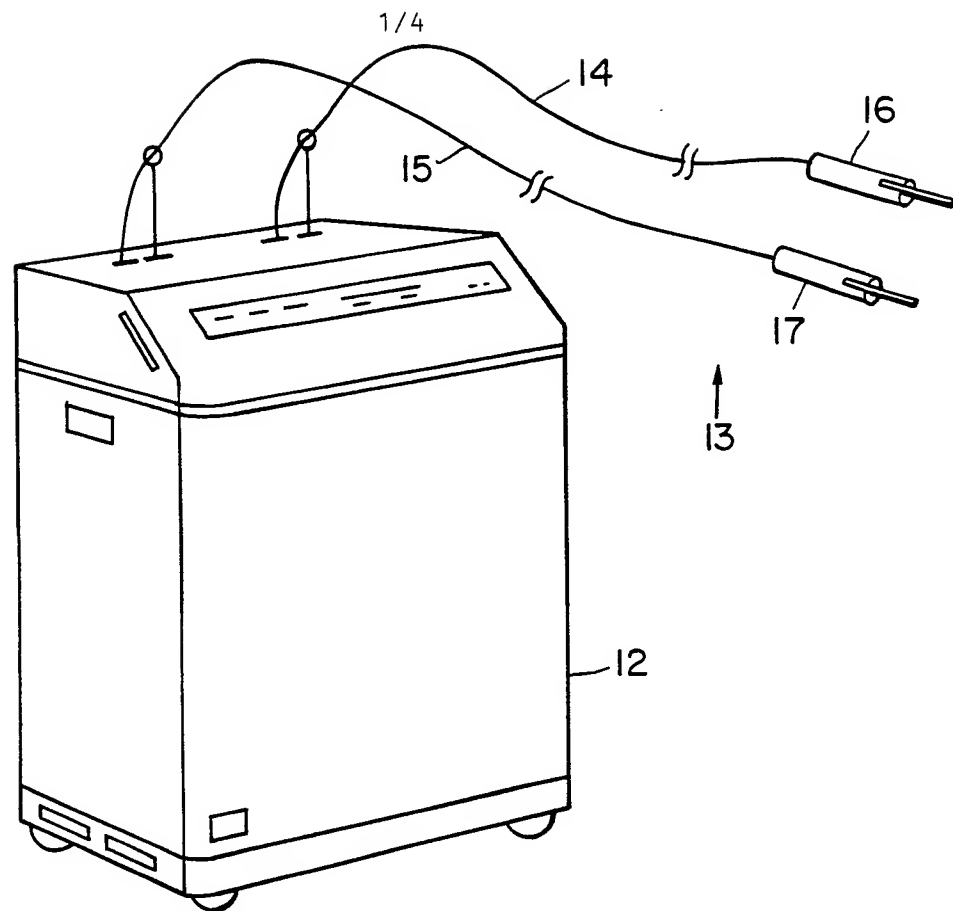
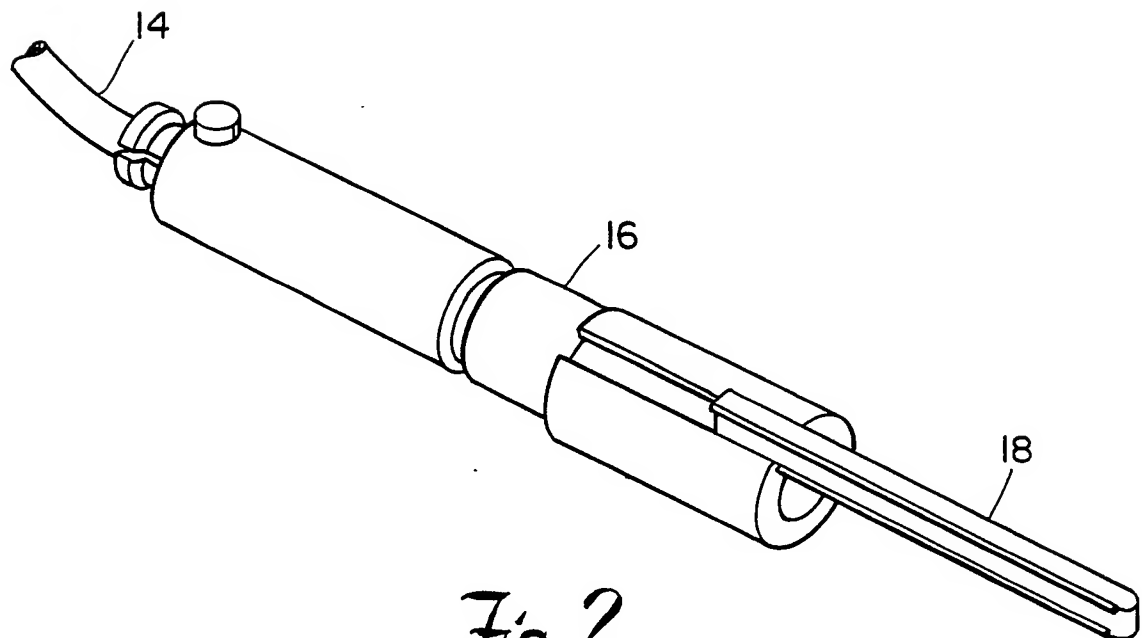
26. An apparatus as claimed in Claim 19, 20, 21, 22, 23
or 24 wherein the liquid core light guide comprises
a liquid having a molecular structure characterized
by the absence of chemical bonds that cause the
absorption of light having wavelengths between 600
and 1100 nm.
27. An apparatus as claimed in Claim 19, 20, 21, 22, 23,
24, 25 or 26 wherein the liquid has a molecular
structure which comprises halocarbons.
28. An apparatus as claimed in Claim 19, 20, 21, 22, 23,
24, 25, 26 or 27 wherein the liquid comprises
tetrachloroethylene.
29. An apparatus as claimed in Claim 19, 20, 21, 22, 23,
24, 25, 26 or 27 wherein the liquid comprises carbon
tetrachloride.
30. An apparatus as claimed in Claim 19, 20, 21, 22, 23,
24, 25 or 26 wherein the liquid comprises deuterated
compounds and inorganic salts.
31. A liquid core light guide having a core diameter of
about 5 mm and capable of transmitting a beam of
laser radiation of a wavelength between 600 and 1100
nm and a fluence of at least 1 J/cm^2 , said light
guide comprising a liquid having a molecular
structure characterized by the absence of chemical
bonds that cause the absorption of light having
wavelengths between 600 and 1100 nm.

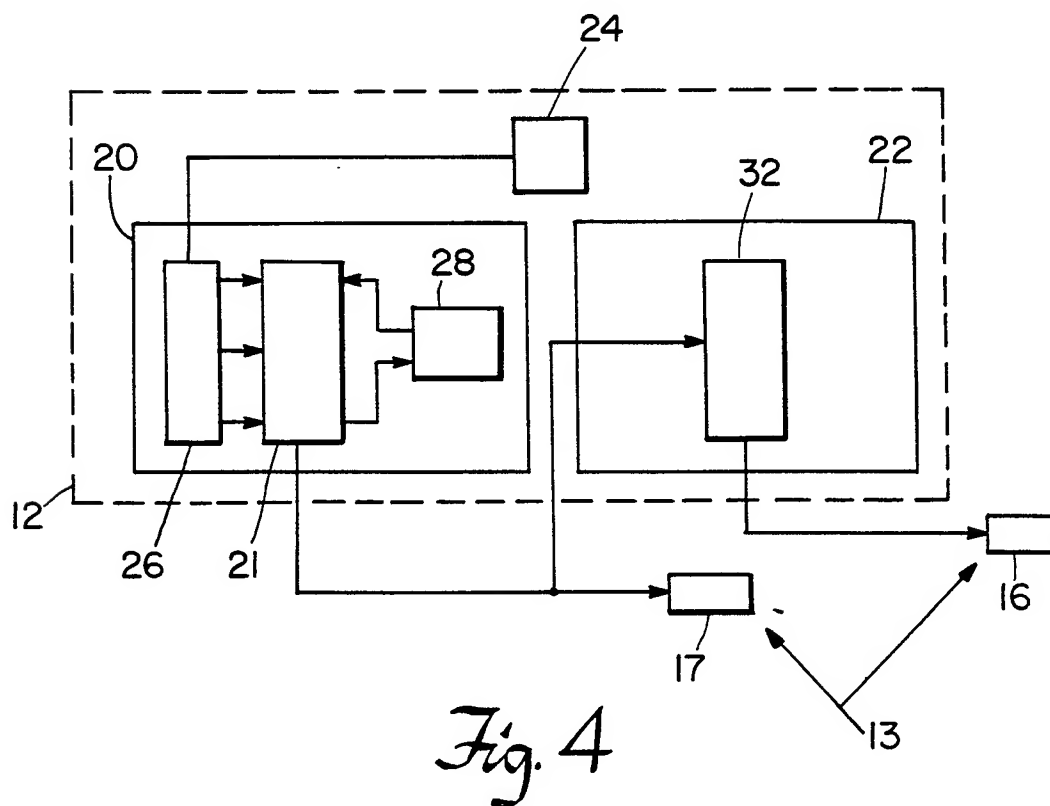
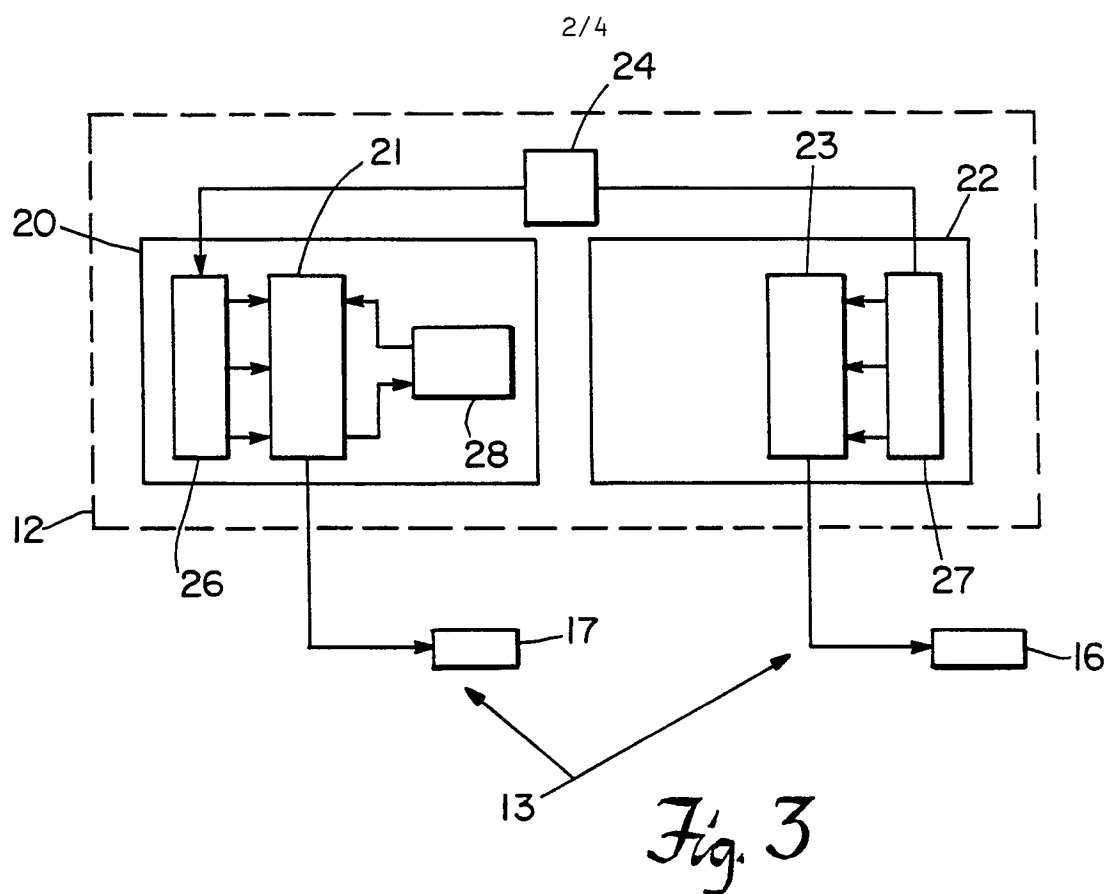
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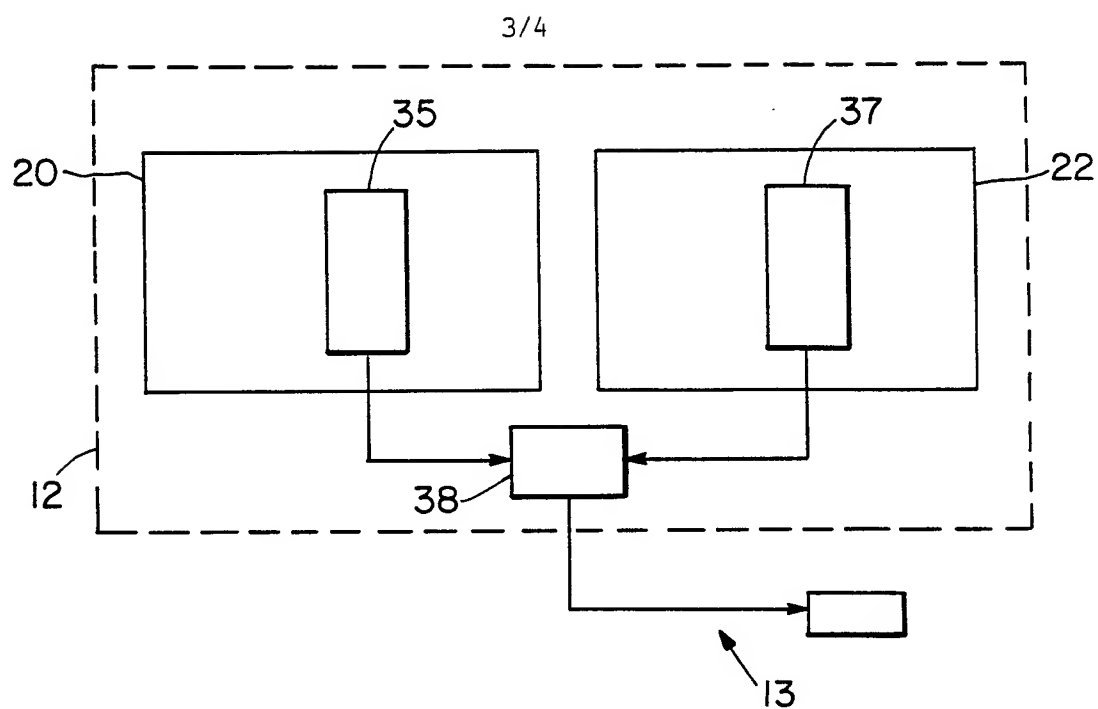
32. An apparatus as claimed in Claim 31 wherein the core diameter is between 3 and 10 mm.
33. An apparatus as claimed in Claim 30, 31 or 32 wherein the light guide further comprises a
5 flexible, thermostable cladding in which the liquid is located, the cladding having a refractive index which is less than the refractive index of the liquid.
34. An apparatus as claimed in Claim 30, 31, 32 or 33
10 wherein the light guide further comprises a pair of windows located at each end of the guide and which seal the liquid within the cladding and a flexible metallic monocoil tube enclosing the cladding.
35. An apparatus as claimed in Claim 30, 31, 32, 33 or
15 34 wherein the liquid comprises halogenated compounds.
36. An apparatus as claimed in Claim 30, 31, 32, 33, 34 or 35 wherein the liquid has a molecular structure which comprises halocarbons.
- 20 37. An apparatus as claimed in Claim 30, 31, 32, 33, 34, 35 or 36 wherein the liquid comprises tetrachloroethylene.
38. An apparatus as claimed in Claim 30, 31, 32, 33, 34,
25 35 or 36 wherein the liquid comprises carbon tetrachloride.

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39. An apparatus as claimed in Claim 30, 31, 32, 33 or 34 wherein the liquid comprises deuterated compounds and inorganic salts.

*Fig. 1**Fig. 2*



*Fig. 5*

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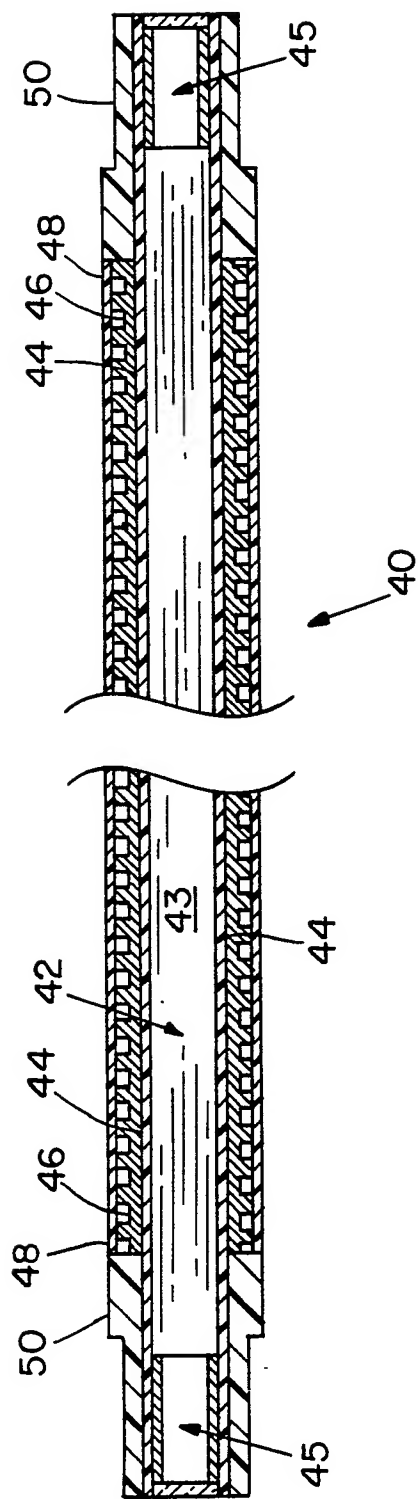



Fig. 6

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61N5/06		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61N ; G02B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	DE,A,2308554 (NATH) 22 August 1974 see the whole document ---	1-12, 15-19, 23-27, 29 30-36, 38
A	WO,A,8704632 (MÜLLER) 13 August 1987 see pages 4 - 6 ---	1-6
Y	Lasers in Surgery and Medicine vol. 1, 1981, USA pages 263 - 276; R.Anderson & J.Parrish: "Microvasculature can be selectively damaged using dye lasers: a basic theorie and experimental evidence in human skin" ---	20-39
Y	EP,A,246552 (HOECHST AG) 25 November 1987 see page 4, lines 28 - 49 ---	20-39
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>^o Special categories of cited documents : ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 09 JULY 1991		Date of Mailing of this International Search Report 18. 07. 91
International Searching Authority EUROPEAN PATENT OFFICE		Signature of Authorized Officer LEMERCIER D.L. 

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9101714

SA 46082

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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09/07/91

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		JP-T- 63503204	24-11-88
		US-A- 4836203	06-06-89
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		JP-A- 62287207	14-12-87
		US-A- 4747662	31-05-88